Challenges to the application of research ethics: researchers' views from Lebanon & Qatar

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Illustrated by Rana Barazi, MD, MPH
Research Team

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- Yara Qutteina, MPH
- Catherine Nasrallah, MPH
Presentation

- Background
- Research Methodology
- Participants
- Major Findings
- Implications
Purpose of the study

• 1. Explore researchers’ experiences of applying research ethics
  ○ Public, private universities
  ○ Lebanon and Qatar
  ○ Social-behavioral and bio-medical research

• 2. Conduct an overview of IRB context specific operations

• 3. Identify areas for future capacity building/intervention
Background

- Increased research funding in the region (Neitzke, 2012)

- No increase in functional ethics review boards in the Middle East (Sleem et al, 2010)

- Adequacy of the ethical review is questionable (Sleem et al, 2010; Kandeel et al, 2011)

- Gaps in knowledge about applied research ethics in Region (Abou-Zeid et al, 2009; and Sleem et al, 2010)
Research methods

2 year study (2012-14)

Methods:

1. In-depth interviews
   • 52 researchers from
     • 10 universities in Lebanon
     • 8 universities in Qatar

2. Survey-Checklist data
   • 5 IRBs in Lebanon
   • 5 IRBs in Qatar

3. Analysis of university websites
   • 23 in Lebanon
   • 10 in Qatar
1. IRB Checklist

• 32 closed-ended Yes/No questions about:
  • IRB registration
  • Members
  • Meetings
  • Procedures
  • Documentation of processes

• Developed from:
  • Human Research Protection Program at AUB
  • U.S Department of Health and Human Services
2. In-depth interviews

- Interview guide:

1. Tell me about the kind of research you do.
2. What kind of research training have you had?
3. What kind of clearance do you need to conduct your research?
4. What do you do to get approval?
5. What kind of challenges do you face from following/abiding by ethical research conduct?
6. What do you need to improve the quality of your research conduct?
3. Website Analysis of unis w HSR

Information on research and research ethics:

- Research related information (research in mission/vision, res. Info)
- Visibility of links (for research and research ethics, dead links)
- Updatedness (2013+)
- Ethics committee roles
- Ethical principles, vulnerable populations & provisions
- Forms/templates available
- Forms of outreach (training, contact information)
Participants
Lebanon

41 Universities

40 Private
1 Public

26 Conduct Human Subjects Res.

21 – no IRBs
5 – have IRBs

10 Participated

9 private
1 public

29 researchers
Participants
Qatar

13 Universities

12 Private

1 Public

10 Conduct Human Subjects Research

4 no local IRB

6 local IRB

8 Participated: 7 private, 1 public

23 Researchers
## Participants

<table>
<thead>
<tr>
<th>Research Area of Participants</th>
<th>Participants</th>
<th>Lebanon</th>
<th>Qatar</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical</td>
<td>15</td>
<td>11</td>
<td>3</td>
<td>26</td>
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<tr>
<td>Health care systems field</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical research</td>
<td>9</td>
<td></td>
<td></td>
<td>9</td>
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<tr>
<td>Public health</td>
<td>7</td>
<td></td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>Social sciences</td>
<td>14</td>
<td>12</td>
<td>9</td>
<td>26</td>
</tr>
<tr>
<td>(Sociology, Anthropology,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychology)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Nutrition</td>
<td>5</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Mental Health</td>
<td>4</td>
<td></td>
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<td>4</td>
</tr>
<tr>
<td>Social Nursing</td>
<td>1</td>
<td></td>
<td></td>
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<tr>
<td>Computer Science</td>
<td>2</td>
<td></td>
<td></td>
<td>2</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>29</strong></td>
<td><strong>23</strong></td>
<td><strong>8</strong></td>
<td><strong>52</strong></td>
</tr>
</tbody>
</table>
Data Analysis

1. Univariate data analysis for checklists
2. Thematic analysis for interviews:

   Interviews transcribed verbatim
   \[\downarrow\]
   Transcripts checked against the recordings and then coded
   \[\downarrow\]
   Codes discussed between research team
   \[\downarrow\]
   Codes manually grouped under recurring themes on spread sheets
FINDINGS

Informed Consent:
Variations in terms, procedures; challenges
Terms describing the consent form

- “Mini”: brief/not inclusive of all the consent form elements
- “Oral”: no signature required
- “Verbal”: meaning oral
- “Written/signed”: participant’s signature required
- “Passive”: the data collector signs the consent form on behalf of the participant
- “Long”: several pages
Terms describing the consent form

- “Information form”: Legal document and medical model
- “Consent letter/templates”
- “Passive consent”: Used when low response rate
- “Oral consent”
- “Verbal consent”: Sometimes used to refer to the process of explaining written consent form info.
- “Online consent”
- “Note”
- “Written consent” / “signed consent”
- “Indirect consent”: consenting by filling questionnaire
Access and entry in Lebanon

Research Site:
- Hospital
- Schools
- Community

Gate keepers:
- Ministry of Health
- Syndicate
- Physician(s)
- Ministry of Higher Education
- School administration
- Municipality
- NGOs
- Key informants
- Pharmacy
- Political party

Consent Sought:
- From In-patient &/or family of in-patient
  - Parents
  - Children / youth
- From Community populations (e.g. adults, out-patients visiting pharmacies)

Consent form as referred to by participants:
- Written consent form for parents
- Assent form for children
- Written consent form for youth
- Written consent form
- Oral consent form
- Mini consent form
- No Assent form for children
- Oral consent form for students
Access and entry in Qatar

Research Site:
- Hospital
- Schools/Universities
- Community

Gate Keepers
- Nurses
- Physician/pharmacist
- Head of department
- Hospital IRB
- Supreme council of Education
- Social worker
- Administration
- Instructor

Consent sought:
- From patient &/or family of patient
- Children/youth
- Parents
- No consent

Consent form as referred to by our participant:
- Written consent form
- Oral consent form
- Verbal consent form
- Written consent form for parents, children & adults
- Assent form for children
- Indirect consent
- Online consent

From Community populations (e.g. migrant workers, out-patients visiting clinics)
- No consent

Note
- Oral consent form
- Written consent form
- Verbal consent form
Challenges to obtaining written Informed Consent

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Lebanon</th>
<th>Qatar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on a <strong>Western</strong> model</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Difficulty with <strong>terminology</strong>/language related to the consent forms</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Participants’ fear of <strong>signature</strong> → not a research culture, lack of trust</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Some <strong>biomedical consent forms</strong> complicated and not understandable</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Difficulty maintaining anonymity, confidentiality and voluntariness</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Very <strong>long</strong></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Too much <strong>information</strong></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Too legalistic</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Consent form not in the participant’s <strong>native language</strong></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
“…parents when they see four big pages of consent form and they wonder why is this, it is frightening for parents. “ (P6)

“…you want to use this in a way that is sensitive to the way we do things and the way we communicate in our culture…” (P7)

“it is also legalistic, and it happens every time, that I went to the class and students would start looking me at me like this (P shows a confused expression) and I said I know it sounds very strange, and I hope it doesn’t make you scared, but the model for the research is medical!” (P35)
“…Yeah, you might see this… that there is what they call it indirect coercion, I mean its just because you are the doctor, they are ready to do everything you want. And this is why we always insist on a way that the treating physician does not consent the patient” (P 39 )

“…They don’t know what there is although you explained to them, they are afraid that you might be stealing something from them…” (P44 )
IRBs and challenges
IRB Checklist Survey Results

- In Lebanon, 5 university IRBs
  Scores on the 32-item checklist ranged bet. 26–32

- In Qatar, 5 university IRBs
  Scores ranged bet. 20–31
<table>
<thead>
<tr>
<th>Item</th>
<th>Score out of 5</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IRB registration</strong></td>
<td></td>
<td>Lebanon</td>
<td>Qatar</td>
</tr>
<tr>
<td>IRB is independent</td>
<td>5</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Registered with Human Research Protection</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Has a mailing address/phone number</td>
<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Renews registration</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>IRB membership</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>At least 5 members</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Both Genders</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Members equally represented</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Heterogeneity from society</td>
<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Members from different academic backgrounds</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Item</td>
<td>Score out of 5</td>
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<tr>
<td>----------------------------------------------------------------------</td>
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<td></td>
<td></td>
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<tr>
<td>At least 1 member with scientific concern</td>
<td>5</td>
<td>5</td>
<td></td>
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<tr>
<td>At least 1 member with non-scientific concern</td>
<td>5</td>
<td>5</td>
<td></td>
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<tr>
<td>Members chosen based on competence in research area</td>
<td>5</td>
<td>5</td>
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<tr>
<td>At least 1 member prof. with vulnerable pop.</td>
<td>5</td>
<td>2</td>
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<tr>
<td>At least 1 member a statistician</td>
<td>3</td>
<td>3</td>
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<tr>
<td>At least 1 member of community</td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Invites people with competence in special areas</td>
<td>5</td>
<td>5</td>
<td></td>
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<tr>
<td>Chair of IRB renewable every 3 years</td>
<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Members serve 1-3 yrs</td>
<td>5</td>
<td>5</td>
<td></td>
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<tr>
<td>Members fulfill CITI</td>
<td>2</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Chair &amp; members audit trainings</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Subcommittees formed to consider expedited review</td>
<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Item</td>
<td>Lebanon</td>
<td>Qatar</td>
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<tr>
<td>----------------------------------------------------------------------</td>
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<tr>
<td>Decisions reported to Full board</td>
<td>5</td>
<td>5</td>
<td></td>
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<tr>
<td><strong>Meetings and procedures</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Written policies for operations</td>
<td>5</td>
<td>4</td>
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<tr>
<td>Written policies for reviews</td>
<td>5</td>
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<tr>
<td>Have Specialized forms</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Meet at least 12 meeting/yr</td>
<td>5</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Agendas sent prior meeting</td>
<td>5</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Meetings are documented</td>
<td>5</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Decisions are documented</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Copies kept of communication</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Acceptability of res. With institutional regulations</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Ensures compliance by reviews</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>
IRBs Described - Lebanon

Healthy Process (+)  Good Role (+)  Total: 6

Police (-)  Radar (-)  Punishing Body (-)  Rate Limiting (-)  Hindering Research (-)  Total: 13
IRBs Described - Qatar

Total: 26
- Cooperative & supportive (4)
- Professional & high standard (2)
- Standardized process (3)
- Necessary for research

Total: 33
- Efficient & Fast (7)
- Research formality (1)
- Proper structure
  - Straightforward
  - Facilitates publications (3)
  - Protects human subjects (2)
  - Friendly
  - Complicated application
  - Becoming Stricter

- Delays (12)
- Inexperienced reviewers (2)
- Multiple submissions (10)
- Challenging process
- Does not fit socio-behavioral research

Necessary for research
- Professional & high standard
- Standardized process

Facilitates publications
- Easy to follow
- Helpful,及时

Complicated application
- Longer process
- More documents

Becoming stricter
- More regulation
- More paperwork

Does not fit socio-behavioral research
- Too bureaucratic
- Too formal

Inexperienced reviewers
- Needed more feedback
- Not very helpful

Multiple submissions
- More than one submission
- More than one IRB
- More than one approval
Advantages and Disadvantages of IRBs

**Advantages**
- Experienced Reviewers 1
- Improves possibilities of publishing 4
- Facilitates research 2
- Facilitates Access 2
- Standardized process 2
- Monitors by providing training and supervision 1
- Protects human subjects 1
- Gives research formality 1
- Sets best practices and standards for researchers from different background 1

**Disadvantages**
- Medical model of ethics not fit for SBS fields 6
- No outreach to researchers 1 Lebanon
  - Continuing educational services
  - Non-existing or failing communication & lack of transparency 5
- IRB membership
  - Inexperienced Reviewers 4
  - Understaffed 1
  - IRB members volunteers 1
- Infrequent meetings 1
- Multiple IRB submissions 10
- Delays 12
“…their presence is very important. I do believe in that, there should be an IRB office. I do believe that there should be IRB reviews… It’s good. It’s a healthy process” (P 1)

“The review boards were quite professional, cooperative… like I said even moved ahead the process …” (P 37)

“IRB generally are not a challenge here, we have really a very supportive environment and we are very well funded, they are very well equipped, really excellent IRB office flowing very nicely although it’s becoming more and more strict” (P 45)

“… one of the things actually that IRB helped us a lot [with], is that when you talk to any stakeholder, organization or a person, when you show them IRB approval, it provides much more confidence with this whole work.” (P3)
“why go back to them if you don’t really trust your ethics review board or if the process is not transparent or if you don’t know how long it is going to take” (P 4)

“I am certainly totally in favor of protecting subjects or participants in research but sometimes it is quite burdensome because it is a medical model” (P 34)

“This is the job of the IRB, to help facilitate and protect the human subjects involved in research. Its not their job to stop or police the research” (P 38)

“Once you have a grant, they will provide you with the ethical approval and sometimes if you have good relationships with IRB members you will get directly the approval” (P 46)
University website analysis
University websites 23+10=33

- Research information accessible (8)
- Research ethics information often not readily available (6)
- ‘Research’ in MS (27), but links to research dead or irrelevant (7/28).
- Links to research ethics committees (15)
- Updated page 2013 (4).
- Updated research ethics page (5)
- Forms/templates available (12): in Arabic (4).
- Ethical guidelines guiding oversight based on:
  - International standards (9)
  - Standards followed by home country campuses (6)
  - National regulatory body- Supreme Council for Health (4)
  - University values (1)
Implications for improving quality of applied research ethics

I. University/Institutional level:

- Improve open and effective communication between IRB and researchers through various channels
- Train IRB reviewers
- Continue to give voice to researchers
- Support cross disciplinary/university collaboration
- More outreach and capacity building for researchers on contextually appropriate research ethics
- Develop IRBs in all universities w HSR
- Institutional accountability for existing IRBs
- Evaluate/ update university websites and pages
II. National level:

- Establish a national IRB/regulatory body
- Encourage collaboration among universities
- Introduce ethics training early
- Require research ethics oversight in all universities - HSR
- Support continuing education programs for research and research ethics
Concluding questions

- To what extent are these statements universal?
  - International research principles and guidelines apply locally.
  - Sound research is ethical research.
  - Research guidelines should be standardized to enhance ethical reviews.
- How do contexts affect sound research fieldwork and consent seeking?
- Are there ‘best practices’ for preparing ethical researchers?
- What kind of preparations should members of IRBs undergo to prepare them for the oversight tasks?
- How should Social/ behavioral research, ex. community based research, be reviewed differently than biomedical research?
If ethics is a study of morality, moral values, right and wrong in social contexts, is it ethical for standardized one size fits all oversight processes?

To what extent are research universities committed to improving the quality of research conduct?

Are western-eurocentric standards the best?

Is IRB accreditation a double edged sword?

NEXT STUDY:

What are participants’/human subjects views/voices?

What do ethics review board members/officials say?