Assessment of Knowledge and Attitude of Ithaca College Graduate Students Toward Protection of Research Subjects

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According to international research ethics guidelines, all research involving human subjects must be reviewed by an Institutional Review Board (IRB) to ensure protection of the rights and welfare of research participants.
Human subject:

✓ A living individual
✓ An investigator conducts research to obtain data through intervention or interaction
✓ Or collect identifiable private information for example from the records

(Code of Federal Regulations, Part 46, Subpart A)
Recent U.S. studies indicate that many health researchers held the attitude that IRBs have been criticized for:

- excessive bureaucracy
- variable practices
- delays in the approval of research
- time consuming process
- responding to redundant inquiries

(Al-Shasi Salman et al., 2007; Burris & Moss, 2006; Drumi et al., 2009; Fost & Levine, 2007; Mallick & O’Callaghan, 2009; Mansbach et al., 2007; Mc Williams et al., 2003; Silverman, Hull, & Sugarman, 2001; Warlow, 2005)
Rationale

- Responsible conduct of research (RCR) courses widely taught in the University (Kalichman, 2011, National Institute of Health, 1992)

- Some research investigating students’ perception regarding RCR in nursing school (Szirony et al., 2004), medical school (Roberts et al., 2007) and in communication sciences (Minifie et al., 2011) but few focusing upon their attitude toward protecting the human subjects
Rationale

- In Ithaca College, there are some schools in which graduate students conduct research on human subjects.
- Hence, evaluation of their knowledge and attitude toward protecting human subjects is important.
Purpose of the study

- To assess knowledge and attitude of Ithaca College graduate students toward the protection of research subjects
Research Questions

Do Ithaca College graduate students have the knowledge to protect research subjects?

Do Ithaca College students have the attitude to protect research subjects?

Variables:

- **DV**: Attitude & Knowledge
- **IVs**: Age, Gender, Department & Prior Course
Method

Study:

- *Type*: multi-department cross-sectional descriptive
- *Time*: November to December 2012
- *Sampling*: stratified sample
Subjects

- **Number**: 50 participants
- **School**: Health Sciences and Human Performance
- **Departments**:
  - Health Promotion & Physical Education (n=7)
  - Exercise and Sport Science (n=15)
  - Occupational Therapy (n=28)
- **Characteristics**:
  - Graduate students
  - Irrespective of sex, race and nationality
  - Agree to participate
  - At least 18 years old
Instrument

- Self-administrated survey
- Developed by Nahed Kandeel and Henry Silverman (Kandeel et al, 2011)
- Consist of 4 main sections:
  - Demographics (age, gender, department)
  - Aware of principles of research ethics and aware of the functions of Institutional Review Board (IRB): (Yes or No)
  - E.g. I attended a course on research ethics
Instrument

- Attitudes towards research ethics: (Likert scale)
  E.g. Research ethics should be taught as a mandatory module at graduate studies

- Attitudes towards IRB: (Likert scale)
  E.g. Ethical review of research enhances trust in research
Instrument

- Likert scale ranging from 1 to 5 ("strongly disagree" to "strongly agree")

- Instrument reliability
  - Cronbach’s $\alpha = 0.71$
Procedures

- Approval from:
  - Department Chairs
  - Instructors of courses
- The graduate students were informed about:
  - Importance
  - Purpose of the study
  - Voluntary participation
  - Right to withdraw from the study at any time without any penalty
  - Not to write their names or ID numbers anywhere on the survey
Participants fill out the anonymous survey (approx. 15 minutes)

Completed surveys placed in drop box marked “Research Ethics Survey” in the back of the room
Analysis

- **Descriptive**
  - Age (Mean ± Sd)
  - Gender
  - Department
  - Prior course
  - Knowledge
  - Attitude

- **Multivariate logistic regression**
  - Association & prediction between the independent variables & the dependent variables
  - Values of R & R Square
The age of the participants is $(23.5 \pm 2.25)$ years.
<table>
<thead>
<tr>
<th>Criteria</th>
<th>Number</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is Research Ethical training programs available for all academics at the School.</td>
<td>15</td>
<td>30%</td>
</tr>
<tr>
<td>I am familiar with ethical principles that govern conducting research involving human subjects</td>
<td>40</td>
<td>80%</td>
</tr>
<tr>
<td>I am fully aware of the function of ethics committees</td>
<td>30</td>
<td>60%</td>
</tr>
<tr>
<td>Do you know that Ithaca College has an ethics committee?</td>
<td>36</td>
<td>72%</td>
</tr>
</tbody>
</table>
Frequency

Research ethics should be mandatory in graduate studies
All investigators should have training in research ethics
Informed consent must be obtained from each participant
There should be measures to protect confidentiality of data
Research subject should not be informed about risks as they may not enroll
Research subject do not understand research, so no need to provide them with details
It is acceptable sometimes to fabricate the data as long as there is no harm to participants

<table>
<thead>
<tr>
<th>Frequency</th>
<th>38</th>
<th>47</th>
<th>48</th>
<th>49</th>
<th>1</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>76%</td>
<td>94%</td>
<td>96%</td>
<td>98%</td>
<td>2%</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>%</td>
<td>88.3%</td>
<td>94.2%</td>
<td>92.3%</td>
<td>95%</td>
<td>12.2%</td>
<td>35.4%</td>
<td>6.4%</td>
</tr>
</tbody>
</table>

Table 3. Attitude toward Research Ethics. Numbers represent percent of respondents who (strongly agree and agree) with the statement (n=50)
There is a need for an IRB in each College because research involving human subjects must be reviewed by IRB. Ethical review of research enhances trust in research. Ethical review of research should be restricted to international collaborative research and projects. Reviewing the research by an IRB would delay research and make it harder for the researcher. The members of ethics committee should be at least professors with high authority in the College. To gain trust in the decision of the IRB, it has to be subjected to supervision by another higher committee.

### Table 4. Attitude toward Institution Review Board (IRB).
Numbers represent percent of respondents who (strongly agree and agree) with the statement (n=50)

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a need for an IRB in each College</td>
<td>44</td>
<td>88%</td>
</tr>
<tr>
<td>Research involving human subjects must be reviewed by IRB</td>
<td>48</td>
<td>96%</td>
</tr>
<tr>
<td>Ethical review of research enhances trust in research.</td>
<td>48</td>
<td>96%</td>
</tr>
<tr>
<td>Ethical review of research should be restricted to international collaborative research and projects</td>
<td>7</td>
<td>14%</td>
</tr>
<tr>
<td>Reviewing the research by an IRB would delay research and make it harder for the researcher</td>
<td>14</td>
<td>28%</td>
</tr>
<tr>
<td>The members of ethics committee should be at least professors with high authority in the College</td>
<td>23</td>
<td>46%</td>
</tr>
<tr>
<td>To gain trust in the decision of the IRB, it has to be subjected to supervision by another higher committee</td>
<td>30</td>
<td>60%</td>
</tr>
</tbody>
</table>

**Egypt**

<table>
<thead>
<tr>
<th>Egypt</th>
<th>85.3%</th>
<th>91.4%</th>
<th>25.1%</th>
<th>32.9%</th>
<th>53.1%</th>
<th>53.1%</th>
</tr>
</thead>
</table>
R: the multiple correlation coefficient = .431, Moderate correlation (.40–.59)
The DV shared 19% of the variance of IVs
Attitude of the students can not be predicted from age, gender, prior course and department, $F(4,43) = 2.448$, $p > .05$
The study shows that Ithaca College graduate students have adequate awareness and a positive attitude toward Research Ethics and IRB.
Limitations: for the generalization of the results

- The **sample size** is small (n=50) because of the time constraint.
- There may be a **selection bias** due to different reasons:
  1. no representation from all schools
  2. not all the students attended the classes (randomization).
  3. some departments had/did not have research methods course.
- Use of a self-report questionnaire (**social desirability bias**), i.e., the tendency of respondents to reply in a manner that will be viewed favorably by others.

Despite these limitations, the present study gives a good idea about the awareness and the attitude of some IC graduate students.
The results yielded some concerns regarding the attitudes of the graduate students toward the IRB, of which one could only hypothesize the factors accounting for such attitudes.

Accordingly, qualitative studies involving in-depth interviews would be able to explore the basis of these attitudes.

Adding some details about the role, function and the procedure of the IRB (Research Method Course)
Any Questions?