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Research article

Graduate students reported practices regarding the issue of informed consent and maintaining of data confidentiality in a developing country

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ABSTRACT

Research involving human subjects requires strict adherence to ethical principles, including informed consent and assuring data confidentiality. Herein, a questionnaire was utilized to assess compliance of graduate students who conduct research involving human subjects in Jordan with proper practices related to informed consent and maintaining of data confidentiality. Among the 251 respondents, 55.4% were from health-related fields, 61.4% undertook research involving humans, and 48.6% did research requiring institutional review board approval. Only 37.1% of respondents reported exposure to research ethics education during their graduate study. Satisfactory adherence to informed consent practices was reported at rates of 56.0%–67.5%. Satisfactory adherence to practices related to data confidentiality and study participants' anonymity was reported at rates of 67.3%–74.7%. Sharing of data or samples with others was reported at a rate of 24.3%. The rates of adherence to proper informed consent practices and practices that maintain data confidentiality were less than ideal. Significant policy changes need to be implemented to address these issues.

1. Introduction

Graduate education is a stage of learning that enables gaining of advanced and specialized knowledge and skills in a given discipline [1, 2]. Among the advanced skills that students gain are in-depth learning, problem-solving, scientific writing, and oral presentation [3]. For graduate programs in biomedical and health fields, students often conduct research involving human subjects. In this context, research ethics should be an integral part of students' scientific training to ensure the rights and welfare of study participants [4]. This includes following appropriate procedures during the informed consent process, guaranteeing voluntary participation, respecting the privacy and confidentiality of research subjects, minimizing harm, ensuring justice, and maximizing benefits [5, 6, 7].

Studies have highlighted the importance of ethics training for students. Such training allows students to obtain the necessary skills needed to ensure responsible conduct of research in their projects [8, 9]. This includes graduate courses, training workshops, and online-specialized and training modules [6, 7, 10]. Therefore, academic institutions with biomedical and health graduate programs are required to invest in education of responsible conduct of research and research ethics.

In developed countries, training of graduate students on research ethics is mandatory by most academic institutions before research onset [11, 12, 13]. For example, the National Institute of Health in the USA requires training on the protection of research participants for all research that involves human subjects [14]. Similarly, training of researchers in ethical principles is required by academic institutions in the United Kingdom [15].

In developing countries, academic institutions are increasingly involved in human research to address and provide solutions for local health problems. However, due to limited research ethics training and inadequate regulation of research activities, the research carried out might be below expectations in terms of ethical standards [16, 17, 18]. Hence, it is necessary to investigate the compliance of researchers in developing countries with research ethics principles, especially when carrying out research involving human subjects. Therefore, the current investigation evaluated graduate students' reported experience with applying research ethics principles related to informed consent and maintaining of data confidentiality during their graduate research that involved human subjects in a developing country. Results demonstrated defects in some of the areas investigated. Hence, it is recommended to review current policies related to human research, perform policy

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changes if needed, and set up mechanisms to monitor and ensure compliance of institutions undergoing research involving human subjects with ethical principles and related research policies.

2. Methods

2.1. Study design and participants

The study utilized a cross-sectional design and aimed at investigating graduate students' reported experiences with applying ethical principles while performing research that involved human subjects. The flow of the study procedures is shown in Figure 1. The study included 251 participants from major Jordanian governmental and private universities. Participants were Master's or PhD students working on or that had completed their thesis or dissertation projects. Students who did not start their projects were not invited to participate. The Institutional Review Board (IRB) of Jordan University of Science and Technology approved the study (ID: 85/117/2018). Informed consent was obtained from all participants as required by the IRB (Supplementary file 1).

The researchers used the G*Power software version 3.1.9.7 to calculate the sample size [19]. A significance level of 0.05, a power of 0.95 and a medium effect size of 0.30 with the minimum number of subjects being 220. Based on an anticipated a dropout rate of 15%, the target number of participants was 253. The researchers performed data analysis on 251 subjects.

2.2. Study instrument

A structured questionnaire was used to collect participant demographics and information regarding graduate students' reported experience in applying ethical principles (Supplementary file 2). Collected demographic data included age, gender, current degree, prior research experience, prior ethics training, research area, and research project status. Concerning research conduct, practices regarding informed consent practices, privacy, confidentiality, and data sharing were collected.

The questionnaire was pilot tested to ensure quality and comprehensibility. Pilot samples were omitted from the final analysis. The reliability coefficient for all items of the survey was >0.6. As for validity, the study survey was face validated via review from experts in the field including senior researchers in the areas of biology, pharmacology, public health, and research ethics. Additionally, to ensure content clarity and comprehension, subjects from the pilot sample were asked to provide comments about the way they understood each item of the survey.

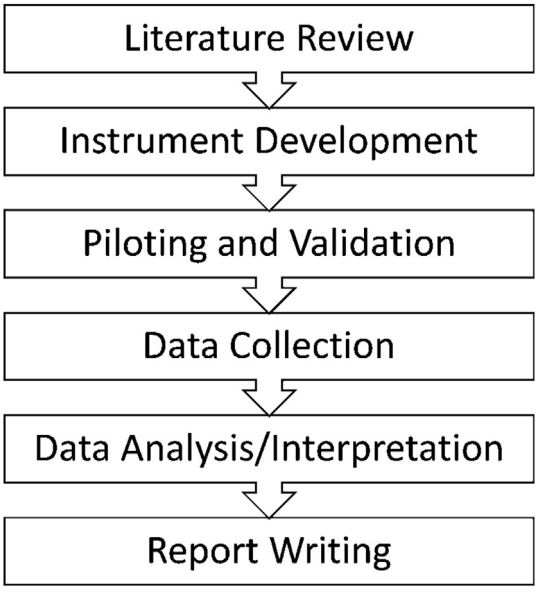

Figure 1. Schematic representation of study procedures.

2.3. Data collection

The study instrument was distributed as hardcopies and electronically using Google Forms during the summer semester of 2018. Participants were current graduate (Master's or PhD) students and graduates of Jordanian universities. Students were recruited to participate from usual students' gatherings at each university campus, such as graduate seminars, conference rooms, and lecture halls. The researcher was available to answer questions from the participants during the filling of the questionnaire.

2.4. Statistical analysis

Data collected using paper questionnaires were added to the spreadsheet obtained from the Google Form. The accuracy of data entry was checked by inspecting 20% of the entered data. Data analysis was performed using the statistical package for social sciences (SPSS; version 23, IBM Inc., Armonk, New York, United States). The chi-squared test was used to compare categorical data. A p-value less than 0.05 was considered significant.

3. Results

The majority of respondents were females (64.5%). The mean respondents age was 26.6 ± 4.9 years. Most respondents were undertaking or had completed their Master's degree (88.8%). More than half of the respondents were from a health-related fields (55.4%), and more than half had completed a research project (62.5%). Less than half had previous research experience. Only 37.1% took research ethics education, and 18.7% indicated that statistical analysis of their research project was performed by individuals not related to the study (Table 1).

Among the respondents, 48.6% (122/251) did research requiring IRB approval. However, strict adherence to informed consent practices was reported in 56.0%–67.5% of all instances (Table 2).

Among the respondents that undertook studies involving humans, 57.1% (88/154) reported including a statement for broad consent during the informed consent process. Additionally, 24.3% (41/169) of the respondents indicated sharing of data or samples with others not related to the study, where 13.6% (9/66) of the instances were among studies not including a choice for broad consent. Finally, the respondents indicated adherence to practices that ensured data privacy and anonymity of study participants in 67.3%–74.7% of instances (Table 3). The associations of participants' experiences including academic degrees, previous research experience, previous research ethics training, and specialty, with their research practices are shown in Table 4. Those in health-related fields specialty were significantly associated with more appropriate research practices in relation to informed consent and data confidentiality.

4. Discussion

This study showed that about two-thirds of graduate students reported applying proper informed consent, including assurance of data privacy practices. This indicates a limited appreciation of students to the absolute requirement of proper informed consent and data confidentiality practices. Moreover, this limited application of proper informed consent processes is in concordance with the fact that graduate students, and even other medical researchers, in developing countries, usually have limited training in research ethics and protection of human subjects during research studies or continuous development/education programs [20, 21, 22]. For example, a study that was conducted in Jordan showed that resident doctors had minimal knowledge of major ethical guidelines such as the Declaration of Helsinki and Belmont Report [20]. The importance of ethics training in the MENA region to advance scientific

Table 1. Participants' characteristics and research related information.

Criteria		n	%
Gender	Male	89	35.5
	Female	162	64.5
Degree	Master's	223	88.8
	PhD	28	11.2
Health-related field	Yes	139	55.4
	No	96	38.2
	Unspecified	16	6.4
Research status	Completed	157	62.5
	Ongoing	94	37.5
Previous research experience	Yes	108	43.0
	No	143	57.0
Research ethics education	Yes	93	37.1
	No	158	62.9
Study statistics performed by	Student	138	55.0
	Mentor(s)	60	23.9
	Others unrelated to the study	47	18.7
	Study did not require statistical analysis	36	14.3

Table 2. Informed consent practices of graduate students undergoing studies involving human subject.

Criteria	Always		Sometimes		Rarely		Not done		NA	
	n	%	n	%	n	%	n	%	n	%
Introduced yourself when contacting potential research participants	110	66.7	36	21.8	5	3.0	14	8.5	86	-
Explained research study when contacting potential research participants	98	59.4	44	26.7	8	4.8	15	9.1	86	-
When contacting potential research participants, emphasized voluntary nature of participation	103	62.8	40	24.4	8	4.9	13	7.9	87	-
Informed potential participants their right to withdraw from study anytime	89	56.0	35	22.0	17	10.7	18	11.3	92	-
Assured potential participants regarding data privacy	110	67.5	31	19.0	9	5.5	13	8.0	88	-

NA: not applicable; graduate students taking the non-thesis track or that are involved in studies not involving human subjects.

research was highlighted in a recent review [21]. Providing mandatory training on protection of human subjects in research studies could significantly improve the responsible conduct of research among graduate students in Jordan and developing countries.

As indicated in the results, a significant portion of graduate students had research projects involving human subjects or human data collection, thus, requiring IRB approval. This emphasizes the importance of educating graduate students and their mentors about the role of the IRB on maintaining of research integrity in academic and research institutions [21, 23]. A study that was conducted on Jordanian health care researchers showed that most of the participants agreed with the importance of the IRB in ensuring the rights, safety, and well-being of the human research subjects [23]. Moreover, the same study highlighted the need for training of IRB members on ethics regulations, including declaration of any conflict of interest with the investigators [23]. Among other important practices that should be ensured by the IRB are the informed consent process, and maintaining of data privacy and confidentiality [24, 25, 26].

In the current study, broad consent was mentioned in 57.1% of instances during the informed consent process in studies involving human subjects. In concordance, a previous study that surveyed informed consent forms extracted from Master's theses of graduate students in two developing countries, showed that major elements were not adequately described in informed consent forms extracted from medical research studies [27]. The respondents of the current study reported sharing of data or samples with other researchers unrelated to the study in 24.3% of

Table 3. Adherence to data privacy and study participants anonymity practices by graduate students undergoing studies involving human subjects.

Criteria	Always		Sometimes		Rarely		Not done		NA	
	n	%	n	%	n	%	n	%	n	%
Data privacy maintained at all research stages	145	74.7	27	13.9	6	3.1	16	8.2	57	-
Utilized codes for participants instead of identifying information during conducting of study	109	67.3	24	14.8	8	4.9	21	13.0	89	-
Utilized codes for participants instead of identifying information during thesis writing	104	67.5	21	13.6	7	4.5	22	14.3	97	-
Utilized codes for participants instead of identifying information during writing of manuscripts for publication	103	69.1	18	12.1	9	6.0	19	12.8	102	-

NA: not applicable; graduate students taking the non-thesis track or that are involved in studies not involving human subjects.

Table 4. Association of participants' experiences and research ethics training with their research practices.

Research practice	Chi-squared test p-value			
	Degree	Research ethics training	Previous research experience	Health-related field
Introduced yourself when contacting potential research participants	0.792	0.271	0.214	0.007[a]
Explained research study when contacting potential research participants	0.527	0.237	0.546	<0.001[a]
When contacting potential research participants, emphasized voluntary nature of participation	0.148	0.087	0.765	<0.001[a]
Informed potential participants their right to withdraw from study anytime	0.764	0.595	0.618	0.010[a]
Assured potential participants regarding data privacy	0.071	0.744	0.170	<0.001[a]
Data privacy maintained at all research stages	0.040[b]	0.561	0.194	0.021[a]
Utilized codes for participants instead of identifying information during conducting of study	0.435	0.654	0.365	<0.001[a]
Utilized codes for participants instead of identifying information during thesis writing	0.039[b]	0.746	0.055	<0.001[a]
Utilized codes for participants instead of identifying information during writing of manuscripts for publication	0.300	0.901	0.193	<0.001[a]

[a] Adherence to practice was significantly associated with being in a health-related field.
[b] Adherence to practice was significantly associated with having a PhD degree.

instances, where 13.6% of these studies did not include a broad consent statement during the informed consent process. This is considered a potential defect in maintaining data confidentiality. In a previous study from Jordan, it has been reported that a majority of potential human research participants had positive perceptions regarding informed consent and its importance [25]. In addition, potential human research participants appreciated the challenges associated with multiple uses of their biological specimens and agreed to the possibility of sharing and utilizing samples for further research [25]. Another study showed that confidentiality and data sharing practices among healthcare practitioners and researchers in Jordan were generally less than optimal [26]. For example, it has been reported that less than half of health data used in the research was not always anonymized or encrypted [26]. In addition, in a study of informed consent forms of studies related to the field of genetics from Jordan, results showed inadequacy in the information provided in informed consent forms, and among the top missing items was a statement ensuring data confidentiality [24]. Thus, when such data are shared for statistical or secondary analyses, participant's privacy, as well as data confidentiality, become potential issues. For example, in the current study, it was reported that statistical analysis was performed by individuals not related to the study in 18.7% of instances. This could compromise data privacy, especially since data anonymization was not utilized, in the current study, in a small but still significant proportion of instances.

In the developing countries, subjects' privacy and confidentiality are still issues not only in research studies but they extend to other field such as health care and human counseling services [28, 29, 30]. In a study from Ethiopia among secondary school students, most of the students reported not using guidance and counseling services due to several challenges, such as confidentiality concerns, and the lack of professionally trained counselors and the required facilities [31].

In the current study no association was found between participants' experiences including academic degrees, previous research experience, and previous research ethics training, with their research practices. This could be related to the nature of these experiences. For example, well-structured research ethics training programs were repeatedly shown to enhance research conduct and practices [21, 32, 33]. However, the structure, comprehensiveness, or topics covered in the research ethics training/education claimed by the current study participants is not known. Further work is needed to assess this point. Moreover, the current results showed that those in health-related fields specialty were significantly associated with more appropriate research practices in relation to informed consent and data confidentiality [24, 26]. This could be related to the types of projects covered within the scope of health sciences that are more likely to involve human subjects, where data confidentiality issues are more prominent.

Among the limitations of the current study is the limited number of similar studies from developing countries. Therefore, comparing the current findings with previous studies was restricted to available literature. More studies are therefore needed to confirm the present findings.

5. Conclusions

In conclusion, graduate students' knowledge and practices regarding the informed consent process and data confidentiality during their research projects were not optimal. These findings highlight serious issues with research involving human subjects in developing countries. The deficiencies reported herein could be attributed, at least in part, to the largely reported lack of education in ethical principles and practices related to research involving human subjects. Thus, it is warranted that graduate students, especially those intending to carry out projects involving human subjects, are offered compulsory training in human research ethics and protection of human research subjects. In addition, developing countries having such issues may need to undergo meticulous review of current policies related to human research and perform policy changes, where applicable, to ensure compliance with ethical principles. Finally, institutions undergoing research related to human subjects, should have set mechanisms to monitor and ensure compliance to research and ethics policies. As this study was exploratory in nature, utilized convenience sampling, and was limited in covering only limited aspects related to informed consent, and data confidentiality and sharing, more comprehensive studies with a wider gamut of research ethics issues are warranted in developing countries.

Declarations

Author contribution statement

S. Swedan: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

O. F. Khabour, K. H Alzoubi, A. A. A. Aljabali: Analyzed and interpreted the data; Wrote the paper.

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Competing interest statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

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