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## Responsible Conduct of Human Subjects Research in Islamic Communities

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### Abstract

In order to increase understanding of the ethical implications of biomedical, behavioral and clinical research, the Fogarty International Center, part of the United States National Institutes of Health, established an International Research Ethics Education and Curriculum Development Award (R25) to support programs in low- and middle-income countries. To develop research ethics expertise in Jordan, the University of California San Diego fellowship program in collaboration with Jordan University of Science and Technology provides courses that enable participants to develop skills in varied research ethics topics, including research with human subjects. The program provides a master's level curriculum, including practicum experiences. In this article we describe a practicum project to modify an existing introduction to human subjects research for a US audience to be linguistically and culturally appropriate to Arabic-speaking-Islamic communities. We also highlight key differences that guided the conversion of an English version to one that is in Arabic. And finally, as Institutional Review Boards follow the ethical principles of the Belmont Report in evaluating and approving biomedical and behavioral human subjects research proposals, we provide observations on the conformity of the three ethical principles of the Belmont Report with Islam.

### Keywords

Human subjects research; Respect for persons; Beneficence; Justice; Pluralistic societies; Islam

### Introduction

The UC San Diego 12-month fellowship program, in collaboration with the Jordan University of Science and Technology (JUST) is funded by the National Institutes of Health (NIH<sup>1</sup>) Fogarty International Center R25 Training program. The goal of the program is to

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#### Compliance with Ethical Standards

**Conflicts of interest** The authors declare no conflicts of interest.

<sup>1</sup>National Institutes of Health. a part of the U.S. Department of Health and Human Services. <http://www.nih.gov/about-nih/who-we-are>.

equip scientists, health professionals and academics who may be involved in teaching research ethics courses or evaluating human subjects research, in low- and middle-income countries, with in-depth knowledge of the ethical principles, policies, and procedures related to international clinical and public health research.<sup>2</sup> The principal investigator and director of the fellowship program, Professor Wael Al-Delaimy chose Jordan to help teach academics and researchers in the Middle East and North Africa, and provide training in responsible conduct of research (RCR) (LaFee 2017), which is defined as the “practice of scientific investigation with integrity”.<sup>3</sup> This is aligned with the requirement for NIH-funded training grants and career development programs to provide training in RCR, and to promote good research practices in various areas, including research with human subjects (NIH 1989<sup>4</sup>; 2009<sup>5</sup>; NIH 2000<sup>6</sup>; Kalichman 2014; Anderson 2016).

A case can be made that an understanding of fundamental principles for making ethical decisions, and addressing the ethical challenges of research with human subjects, is particularly important to researchers involved in international biomedical research, where culture, religion, diverse regulations and policies become key factors in considering responsible research practices (Alfano 2013), and where researchers have to strike the right balance between universally accepted ethical practices and conflicting traditional customs (Marshall 2005), or beliefs. In other words, the multi-national nature of research raises unique challenges; reconciling conflicts between the research community beliefs with the investigator’s beliefs, and conducting research in resource-poor areas where human subjects may be insufficiently protected from exploitation (Marshall 2005). Therefore, these challenges should be taken into account by researchers who implement research in pluralistic societies, where research participants come from different backgrounds and cultures (Niebroj 2010). In this regard, cultural respect would enable human subjects researchers to understand the needs of groups participating in research in an inclusive partnership (National Institutes of Health, Cultural Respect 2015), and would enable researchers to avoid stereotyping and accommodate diversity within groups (Kodjo 2009).

Research ethics training should foster a community focus (Kalichman 2013), i.e., encourage researchers to engage their non-scientific communities to identify common values. However, this cannot be achieved if trainees are not familiar with the relevant rules and the ethical principles that ensure rights of human subjects are protected, or options and resources for RCR appropriate to their country or institution, as they may not be able to find the people or the resources to help them address the ethical challenges they may encounter in the conduct of research.

While researchers involved in the design, review, or conduct of research with human subjects are typically introduced to ethical principles as outlined in the Belmont report<sup>7</sup> and the Declaration of Helsinki,<sup>8</sup> the concomitant impact of religion on perceptions of research

<sup>2</sup><https://grants.nih.gov/grants/guide/pa-files/PA-16-081.html>.

<sup>3</sup><https://jordanrcrprogram.com/>.

<sup>4</sup>[http://grants.nih.gov/grants/guide/historical/1989\\_12\\_22\\_Vol\\_18\\_No\\_45.pdf](http://grants.nih.gov/grants/guide/historical/1989_12_22_Vol_18_No_45.pdf).

<sup>5</sup><http://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html>.

<sup>6</sup><http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

<sup>7</sup>Belmont Report (1979) <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>.

<sup>8</sup>Declaration of Helsinki (2008). <http://www.healthscience.net/resources/declaration-of-helsinki>.

participants or their communities about human subjects research should not be underestimated. A question likely to be asked, and which biomedical researchers should be prepared to answer, is: To what extent is the conduct of research aligned with religious beliefs and perspectives? For example, the ethical dilemma of evolving stem cell research, which can involve the use and destruction of human embryos (even knowing that they would have been destroyed for other reasons anyway), or therapeutic cloning, has garnered significant debate and skepticism in religious circles (Fadel 2012).

As a participant in the UC San Diego Fellowship program in Jordan, one of us (AA) anecdotally observed that the program's numerous online group discussions typically include at least one question, response or comment about the Islamic viewpoint regarding certain research topics. A noteworthy example in practice is that dental practitioners have observed that religious perspectives play a major role in patients' decisions to avoid dental treatment during Ramadan, the month of fasting in the Islamic calendar, out of fear that even routine dental procedures might break their fast (Al-Khatib, first hand unpublished observation confirmed by personal communication with many dental practitioners). These observations suggest that it is important for researchers to be equipped with knowledge and understanding of religious perspectives with respect to human subjects research.

Section one of this paper describes the process we used to develop an Arabic version of the human subjects topic, one of the topics recommended by the NIH for RCR education (NIH 2009). Section two highlights the key differences between the University of California San Diego human subjects topic (UCSD HS) and the Arabic human subjects topic (Arabic HS). In section three, we discuss the Islamic perspective on the three principles of the Belmont report, articulating questions to be considered in the conduct of research with human subjects. The aim was to produce a document that is linguistically and culturally applicable for Islamic communities.

## Process for Developing a Resource on the Topic of Human Subjects

Overview: an English introductory document on the topic of human subjects research (<http://research-ethics.net/topics/human-subjects>) was revised and used to develop an Arabic document. To promote relevance to the Jordanian and Islamic communities, key changes were introduced: adding questions to original cases, two additional cases, information about relevant laws/regulations, and a section on the Belmont report and Islam.

Researchers involved in the design, review, or conduct of human subjects research would benefit from resources that introduce the topic of human subjects research, providing information about laws and regulations that govern research with human subjects, and an overview of the steadily increasing, and overlapping standards and guidelines from diverse regional and international organizations (Pavone 2012). Ethical challenges likely to arise when researchers formulate research questions, prepare proposals, and implement human subjects research often include dilemmas pertinent to religious concerns. This is likely to be particularly important to the principle of distributive justice: Underestimating the impact of culture and religion on the perception of potential participants, or communities including researchers, may lead to an unjust allocation of the benefits and burdens of research in

certain societies (Benatar 2001). In short, if resources are simply translated word for word from a foreign culture, or do not address the conceptual use of language-specific vocabularies, then community laws and values may be perceived as being imposed, irrelevant or illogical, and thus would not be implemented either ethically or efficiently. To make it easier for human subjects researchers to “do the right thing,” and to develop a resource that can be used to promote good research practices, we began with an introductory document prepared by Professors Michael Kalichman and Dena Plemmons of the University of California, San Diego (UC San Diego),<sup>9</sup> on the topic of human subjects research (<http://research-ethics.net/topics/human-subjects>) (UCSD HS). This material was used as a starting point to develop an Arabic version of the human subjects topic (Arabic HS). Because the goal was to provide a revision that is linguistically and culturally appropriate to Arabic-speaking Islamic communities, we made changes such as those summarized in Table 1. In all cases, the goal was to assist researchers to ethically meet the challenges of designing, reviewing, and conducting human subjects research when questions about the applicable laws and/or Islamic perspectives are likely to be raised. Arrangements are being made to ensure that the complete, finalized document in Arabic will be freely available online.

## What are the Key Differences Between UCSD HS and Arabic HS and Why?

Although the two versions have much in common, they differ in several aspects. In the following sections, we review the existing and revised versions, discussing the rationale for and detailing of key differences between UCSD HS and Arabic HS.

### Key Differences in the Relevant Laws and Regulations

Because human subjects researchers' conduct should comply with the legal requirements of human subjects research, researchers are charged with familiarizing themselves with applicable laws and regulations. Therefore to answer the question of which law applies in Jordan, we contrasted U.S. laws and regulations issued by federal agencies with human subject requirements such as the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), and the National Science Foundation (NSF) with relevant versions of Jordanian laws and regulations that govern human subjects research such as the Law of Clinical Studies No. 2 (2011), Public Health Law No. 47 (2008) and its amendments, and the Regulations for Insurance on Research-Related Injury (2013). However, it should be noted that an exhaustive list of potentially relevant laws and regulations was not possible, and researchers must be cognizant that laws are not static. New laws are frequently enacted and existing laws can be amended.

To equip human subjects researchers with the requisite knowledge as to which body or organization has regulatory oversight for human subjects research, in the Arabic HS, we described the roles of a central agency like the Jordanian Food and Drug Administration<sup>10</sup> (JFDA) and Institutional Review Boards in protecting the rights and safety of those who volunteer in human subjects clinical research.

<sup>9</sup><http://research-ethics.net> (R-E.net) Resources for Research Ethics Education.

<sup>10</sup><http://www.jfda.jo/>.

## Key Differences in Case Studies

As tools for discussion, UCSD HS includes three cases. Because the cases remained largely appropriate for Arabic and Islamic communities, we decided to add some questions to reinforce relevance, but further added two new cases. The two revised cases and the three new cases are summarized below:

1. UCSD HS Case #1 raises the issue of how to handle incidental findings in genomics biomedical research when the wishes of a research participant are not known (e.g., Wolf et al. 2012). For Arabic HS Case #1, we added two questions: the first was about the applicability of an Islamic rule “nobody is allowed to dispose of another’s property without their consent” (Ghaly et al. 2016); in addressing the issue of participants’ right to know and their right not to know. The relevance of this rule to human subjects research can be illustrated by a hypothetical. This Islamic rule would be violated if a researcher fails to explore whether or not a research participant wishes to be informed of an incidental finding, and then fails to disclose an incidental finding that could have an impact on the participant’s health. To help the readers understand this Islamic rule, a non-medical example would be if a person authorizes someone to sell his car, and during the inspection of the car, a diamond ring is found. The person, who is authorized to sell the car, should not sell or dispose of the ring without the owner’s permission. The second question was about whether the concept of informed consent as an ongoing process, i.e., not simply a single event or a signature, can justify making Institutional Review Board (IRB) approval contingent on exploring the wishes of a research participant; that is, whether she should or should not be informed about an incidental finding. These two questions were included in the Arabic HS so that human subjects researchers would be encouraged to consider the ethics of and possible solutions to the dilemma of incidental findings in genomics research.
2. UCSD HS Case #2 raises the issue of protecting subjects enrolled in clinical trials. The Arabic version of UCSD HS Case #2 has an added question about the legal implication of requiring insurance coverage as stipulated in Jordanian law, for human subjects enrolled in clinical trials.<sup>11</sup> The aim is to promote due diligence and protection of participants’ rights by human subjects researchers, by highlighting the need to anticipate side effects, such as an allergic reaction to a trial medication, and to be prepared to provide appropriate management should adverse effects arise.
3. UCSD HS Case #3 initiates discussion regarding the use of unethically obtained data, e.g., from Nazi Germany, or data obtained by enrolling subjects in human subjects research without informed consent. For the Arabic HS Case #3, we added the following question: “Does the “public interest overrides individual interest” rule justify the use of unethically obtained data? What about serving the public interest by providing protection for human subjects against violations, and

<sup>11</sup>The Jordanian Law of Clinical Studies No. 2 (2011) requires insurance coverage for human subjects enrolled in clinical trials. [http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/50\\_211.pdf](http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/50_211.pdf).

preventing human cruelty in the name of research?” This question was added to encourage discussion about the societal ramifications of allowing the use of unethically obtained data and to foster reflection by researchers about the need to consider public interests. The outcomes are to ensure the safety and well-being of research participants and to prevent exploitation of vulnerable groups.

4. A new case (Case #4) added to the Arabic HS version raises the issues of conflict of interest and recruiting subjects for a clinical trial before obtaining approval of an IRB. The purpose of this case is to initiate discussion about: (a) adherence to the requirement for IRB approval before beginning a clinical trial; (b) conflicts of interest in biomedical research and how they can be minimized or removed; and (c) ethical, legal and religious requirements that call for insurance coverage for research participants prior to enrolling in clinical trials. These issues are of particular relevance to Islamic communities and consideration of these issues is likely to promote researchers’ adherence to best research practices.
5. Case #5, also newly created for the Arabic HS version, explores the collection of bio specimens for a specific research purpose and then using those specimens for a different purpose, or allowing use by an unauthorized person. Questions asked are designed to foster reflection and learning about the ethical, legal, and religious requirements for reporting incidental findings pertinent to contagious diseases such as Tuberculosis, even if the issue of handling such findings arises through unauthorized use of participants’ bio-samples. In addition, this case study is intended to equip researchers with the skills they will need for situations or dilemmas where it is necessary to strike a balance between relevant competing interests and principles.

### Reflections on the Belmont Report and Islam

As mentioned above, it cannot be assumed that teaching research ethics to human subjects researchers in Islamic communities will be meaningful and effective if resources heavily rely on foreign, word to word translated guidelines that do not address the Islamic cultural dimension of ethical human subjects research. In Islamic communities, religion greatly influences behavior and practice (Serour 2008), like other religions (Isaac et al. 2016). Undoubtedly, researchers must face questions of how each of the principles of the Belmont report intertwines with Islamic law, irrespective of where a human subject study is undertaken. If researchers working in Islamic communities or with religiously-motivated research subjects fail to promote responsible research practices because they are skeptical or ignorant of the religious perspective of human subjects research, and/or its ultimate potential in providing medical benefits and improving the wellbeing of humans, people in Islamic communities will lose trust in researchers. As noted by Titus and Ballou (2014), research integrity is damaged, or diminished when researchers engage in questionable research practices. The consequence in this case could be that Islamic communities would be deprived of the benefits of human subjects research. According to the National Institutes of Health (2015), poor medical research planning that does not take into account the principles of cultural respect, may yield inappropriate results. Indeed, it bears noting that any attempt to investigate sensitive topics that are considered taboo in religion-motivated communities, is



likely to yield unusable results. With that in mind, in the Arabic HS version, we included a section in which we discuss conformity of the three ethical principles of the Belmont Report with Islam, citing evidence, shown in Table 2, from primary sources of Islam (Al-Aqeel 2009). Our purpose is to equip researchers with knowledge to further explore, initiate and engage in any discussion of relevance to the ethics of biomedical and behavioral human subjects research.

## **Ethical Principles of Human Subjects Research: Is the Belmont Report Compatible with Islam?**

The Belmont Report is a major document used by IRBs in guiding the evaluations of biomedical and behavioral human subjects research (Vollmer and Howard 2010). It is a “statement of basic ethical principles and guidelines that should assist in resolving the ethical problems surrounding the conduct of research with human subjects”.<sup>12</sup> This statement identifies three basic ethical principles, or rules that researchers should adhere to (Vollmer and Howard 2010): respect for persons, beneficence, and justice.

### **Respect for Persons**

This principle “incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.”<sup>13</sup>

Respect for persons is a core principle of the ethics of human subjects research; therefore, researchers have to show that their research proposals address this primary principle from the beginning to the end of their research, as well as after the research ends.

Respect for persons is expressed in the fulfilment of at least three key requirements: (a) any human subjects research must be approved by an institutional review board (IRB); (b) participants in human subjects research, especially if any potential harm to subjects is expected, including minimal harm, give their voluntarily explicit informed consent to participate; (c) vulnerable subjects such as prisoners and the incapacitated should either be provided with sufficient additional protections or excluded from the research.

The principle of respect for persons, i.e., autonomy from an Islamic perspective has been previously studied. Fadel (2010), a member of a group that discussed a revised Arabic version of the International Ethical Guidelines for Biomedical Research involving Human Subjects, translated by the Islamic Organization of Medical Sciences (IOMS), showed that after an in depth study of this principle, the group, including Muslim scholars, concluded that the principle of respect for persons is consistent with Islamic rules. Fadel (2010) elaborated that in Islam, a similar principle applies, that is, “[n]o one is entitled to dispose of the right[s] of [a] human being without his [her] permission.” In human subjects research context, this implies that “no one should be involved in a research project without his[/her]

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<sup>12</sup><https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.

<sup>13</sup><https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.

free and voluntary consent”. This statement is arguably in conformity with the Belmont principle of respect for persons.

However, Packer (2011) noted that in obtaining informed consent from a Muslim patient, it is reasonable to remember that absolute autonomy is rare, as there will often be feelings of responsibilities to God. While this may be true for some research participants, this observation cannot be generalized. By the same logic, one can reasonably ask if a dying mother has absolute autonomy when she has a feeling of responsibility toward her infant, for example. However, since informed consent addresses each participant’s right to decide what can be done and what cannot be done to their body, researchers should remember that the process of obtaining informed consent should show respect to their faith as well (Rathor et al. 2011), and that their whole being is considered (Mueller et al. 2001). In this context, cultural respect (National Institutes of Health 2015) implies that if a participant may be concerned about the presence of a religiously prohibited ingredient in a trial medication or placebo, the medical researcher has an obligation to disclose the ingredients to him/her during the process of informed consent. However, in real life, efforts to consider the whole being of research subjects may not be an easy task; especially given that respect for persons has a *prima facie* requirement to protect the privacy of research participants. Thus, many questions can be raised, such as: are female research participants treated as autonomous subjects, when there is a religious or statutory requirement to obtain approval of a male guardian before enrollment in clinical trials? How much information, if at all, can be disclosed to the husband of a female research participant? These and similar questions are worthy of further discussion and research. Interestingly, Torry (2017) argues that “an equality agenda and patient autonomy make religion feel like a difficult issue to handle”, referring to religion as “an increasingly important element not only in many patients’ lives but also in the lives of many practitioners”.

## Beneficence

According to the Belmont Report, “two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms”. The Belmont Report requires that human subjects researchers observe the obligation of beneficence in their research projects. In doing so, they should consider at least four key concepts: (1) IRBs and investigators are obliged to give “forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation”; (2) “Members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.”; (3) In the process of learning what is harmful and what is beneficial, subjects may be exposed to certain risks, and that would require researchers to “decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks”<sup>14</sup>; and (4) Researchers should understand that observing the principle of beneficence is likely to come in conflict with other principles and may raise

<sup>14</sup><https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.



ethical challenges in the context of human subjects biomedical research. Therefore, an attempt to strike the proper balance is an obligation under this principle.

Exploring the Islamic perspective of the principle of beneficence depends on understanding the five goals, i.e., purposes, of Islamic law (*Shari'a*) which are: the protection of religion, the protection of wealth, the protection and preservation of life, the protection of [mind], and the protection of progeny (Afifi 2007). Clearly, the last three goals have prima facie relevance to the principle of beneficence, and are at the heart of human subjects research, because it can also be affirmed that research involving human subjects is central to the process of achieving the goals of Islamic law. In this context, many questions might be raised. For instance, can the purpose of the protection of mind be achieved without investigating the etiology, or the prevalence of certain diseases such as schizophrenia or Alzheimer's disease? Or how would the purpose of protecting progeny be achieved without investigating risk factors, and developing infertility treatments? Thus it can be argued that developing medications, finding cures and epidemiologic studies are essential to the purposes of Islamic law with respect to the protection and preservation of life, mind and progeny. In addressing the issue of balancing possible harms against benefits, human subjects researchers, faced with ethical challenges of relevance to religious concerns, can apply Islamic rules such as: public interest overrides individual interest; accept the lesser of two harms; necessity overrides prohibition; harm has to be removed at any cost if possible (IMANA Ethics Committee 2005); and "if a less substantial instance of harm and an outweighing benefit are in conflict, the harm is forgiven for the sake of the benefit" (Fadel 2010). On the issue of harm, it bears noting that different cultures may think of harm differently, because harm is a broad and abstract concept, it includes physical, emotional, mental, and financial injuries, damage to reputation or social status, and it can also mean negative consequences or complications. Because religion can influence what actions constitute harming a person, human subjects researchers should be cognizant that what may constitute harm in a religiously-motivated culture may be perceived as beneficent in another culture. Walton et al. (2014) explored the health beliefs of practicing Muslim women, and found that all research participants (100%) strongly agreed that smoking, alcohol and overeating were harmful to the body. So, while consuming alcohol is considered to be a harmful action, and is thus prohibited by Islam, and is even illegal in some Islamic communities, it may be considered beneficial in other cultures.

## Justice

According to the Belmont Report, the principle of justice in the context of human subjects research implies that the selection of research subjects needs to be scrutinized to ensure that research participants are selected for reasons directly related to the problem being studied, and that "an injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly...". Therefore, the application of the principle of justice primarily requires addressing the following issues: (1) Researchers "should not offer potentially beneficial research only to some patients who are in their favor or select only 'undesirable' persons for risky research." (2) Researchers should determine which classes of subjects should be included or excluded in any human subjects research and why. (3) Researchers should consider the order of preference in the selection of classes of

subjects (e.g., adults before children). (4) Researchers should avoid increasing the burden of research on the already burdened (e.g., the institutionalized, the very sick) and (5) Researchers should be aware of social, racial, sexual and cultural biases in the selection of research subjects, and thus can consider distributive justice.<sup>15</sup> Unfortunately, this is easier said than done (Gillon 1994).

The principle of justice is an established principle in Islamic law, and it calls for fairness in all affairs of life, including the context of human subjects research. Simply put, in true Islam, injustice is forbidden. Coercing and exploiting vulnerable groups to participate in research is incompatible with Islamic law, as is excluding women of reproductive age from biomedical research (Fadel 2010). Gillon (1994) subdivided the principle of justice into three categories: respect for people's rights (rights based justice), respect for morally acceptable laws (legal justice) and distributive justice (Benatar 2001) which means fair distribution of scarce resources. Distributive justice is of paramount importance in a pandemic, for example, where there is no satisfactory medication, and a test drug shows promising benefits. When research will potentially provide a cure by enrolling patients in a trial, researchers would have to decide how to distribute the trial medication. Clearly, their decision has to be just, fair and ethically justifiable, based on one fundamental assumption: Injustice in selecting participants is forbidden. However, in agreement with Gillon (1994), defining the scope of justice is an impossible task. So, even though injustice is forbidden, ensuring justice in the selection of participants for human subjects research is perhaps viewed as aspirational rather than readily achievable.

## Conclusion

Without delving into the interpretation of the primary resources of Islam, i.e., the Quran and the Sunnah<sup>16</sup> (Kamali 1991), or different schools and doctrines of Islam (Al-Aqeel 2009), as they are not within the scope of this paper, this document is intended to alert researchers working with human subjects to issues that they need to address, particularly when faced with questions concerning the conformity of Islamic principles with the principles of the Belmont report. The goal is to articulate some questions that human subjects researchers may face, not only in Islamic countries, but also in pluralistic societies. In developing introductory material on the topic of research with human subjects, we recommend that a version that is linguistically and culturally suitable should include a section with relevant laws and regulations that govern human subjects research where research involving human subjects is implemented, as well as a section that includes quotes, or principles from pertinent religions, faiths or cultures in situations where religion or faith is likely to guide research subjects decisions. Nevertheless, the intention is not to provide a religious translation of the human subjects research topic. Rather, the aim is to help researchers acknowledge the possible concerns of religiously-involved research subjects, and to encourage researchers to engage their communities in meaningful discussions about religiously endorsed responsible human subjects research practices. Finally, it is important to note that satisfying the ethical principles of the Belmont report does not automatically mean

<sup>15</sup><https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.

<sup>16</sup>*Sunnah* is the second primary source of Islam; it supplements the Quran and interprets its rulings.

that a particular human subjects research project is ethical. Therefore, this paper would not be complete without highlighting the “moral obligation to ensure that all research is carried out in ways that uphold human rights, and respect, protect, and are fair to study participants and the communities in which the research is conducted. Scientific and social value cannot legitimate subjecting study participants or host communities to mistreatment, or injustice”.<sup>17</sup>

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<sup>17</sup><https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>.

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**Table 1**

A comparison between the outlines of the UCSD HS and Arabic HS

UCSD HS	Arabic HS
Summary	Summary translated, no additions
Background	Background translated, no additions
Principles of the Belmont report	Principles of the Belmont Report edited with examples to increase the understanding of the three principles so that contextualization is not lost in translation
Regulations and guidelines	Replaced the examples of federal regulations with the pertinent Jordanian laws and regulations, and a description of the role that the Jordan Food and Drug Administration (JFDA) plays in protecting human subjects in clinical research
Three case studies	Five case studies: we added culturally relevant questions to the original cases, and added two more cases relevant to the Jordanian and Islamic communities
Discussion questions	Arabic translation of the original discussion questions
Additional considerations	Under additional considerations, we added a section on the Belmont Report and Islam with quotes from the Quran and the Sunna

**Table 2**

English translation of religious quotes used in the Arabic HS section on the Belmont Report and Islam

Belmont report principles	Quotes from primary sources of Islam
Respect for persons	"We have honoured the sons of Adam" (The Quran. Al-Israa [111]: 70) <a href="http://www.searchtruth.com/chapter_display.php?chapter=17&amp;translator=2&amp;mac">http://www.searchtruth.com/chapter_display.php?chapter=17&amp;translator=2&amp;mac</a>
Beneficence	"...and make not your own hands contribute to (your) destruction; but do good; for Allah loveth those who do good" (The Quran. Al-Baqara [286]:195) <a href="http://www.searchtruth.com/chapter_display.php?chapter=2&amp;translator=2&amp;mac">http://www.searchtruth.com/chapter_display.php?chapter=2&amp;translator=2&amp;mac</a>  "There is no harm or reciprocating harm against others" <a href="http://dailyhadith.abuaminaelias.com/2016/08/15/hadith-on-harm-there-is-no-harm-or-reciprocating-harm-against-others/http://www.alukah.net/sharia/0/88230/">http://dailyhadith.abuaminaelias.com/2016/08/15/hadith-on-harm-there-is-no-harm-or-reciprocating-harm-against-others/http://www.alukah.net/sharia/0/88230/</a>
Justice	"The blame is only against those who oppress men and wrong-doing and insolently transgress beyond bounds through the land, defying right and justice: for such there will be a penalty grievous" (The Quran. Ash-Shoura [53]: 42) <a href="http://www.searchtruth.com/chapter_display.php?chapter=42&amp;translator=2&amp;mac">http://www.searchtruth.com/chapter_display.php?chapter=42&amp;translator=2&amp;mac</a>  "O My servants, I have made oppression unlawful for Me and unlawful for you, so do not commit oppression against one another" <a href="http://muslimjapan.com/304.html?lang=en">http://muslimjapan.com/304.html?lang=en</a>  "Beware of injustice, for injustice will be darkness on the Day of Resurrection" <a href="http://dailyhadith.abuaminaelias.com/2016/01/21/hadith-on-injustice-beware-of-injustice-obscenity-immorality-greed-and-violence/">http://dailyhadith.abuaminaelias.com/2016/01/21/hadith-on-injustice-beware-of-injustice-obscenity-immorality-greed-and-violence/</a>

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