Research article

Researchers’ ethical perspective about women participation in research studies in Jordan

Zeinab Y. Al Subeh, Karem H. Alzoubi

Faculty of Pharmacy, Jordan University of Science and Technology, Irbid, Jordan

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ABSTRACT

Women participation in research studies has been an issue especially in developing countries with conservative cultural and religious beliefs. This study was aimed to assess researchers about ethical and cultural issues related to the women participation in research studies. A descriptive cross-sectional questionnaire-based survey was conducted among researchers from different health disciplines in Jordan. Results showed that to encourage females’ participation in research studies, majority of the researchers (66.7%) indicated that they will always preferably consider hiring a female research assistant for studies that include female participants, especially when the study protocol involves direct contact with participants. Additionally, large proportion of researchers believed that females are more likely to avoid research studies if they involve overnight-stay outside home (87.5%), performing physical exercise (72.2%) or smoking tobacco products in non-private room at the research center (68.8%). Finally, 31.3% of researchers disagreed that women in society of Jordan have the freedom to decide on research studies participation, and 47.2% of researcher respondents indicated that females must seek the consent of male relatives, such as father, husband, brother, or other family member upon her participation in research studies. In conclusion, researchers in Jordan are considerate to cultural and religious norms. Researchers who are unfamiliar with the norms of culture must consider barriers discussed in the current study to increase the participation rate of female in their research studies.

1. Introduction

In the past decades, there were several concerns surrounding women inclusion as research subjects, and the involvement in clinical studies were mostly excluded to men (Kwiatkowski et al., 2013; Mastroianni et al., 1994). However, recruiting women to participate in research studies became highly important these days for various reasons (Bird and Rieker, 1999; van der Graaf et al., 2018). First, significant recruitment of both men and women is required to enhance the generalizability of outcomes of research on the general population (ACOG, 2015; National Institutes of Health, 2015). Second, there is a lack of data related to health and diseases in women that further forces for women inclusion in clinical trials to fill this gap in knowledge diseases. In addition, treating women depending on scientific evidence that comes from men-based research could lead to suboptimal treatment for women (Beauchamp and Childress, 2016; Vitale et al., 2017). As a result, research practice had several changes, including the change in the design of studies to increase the proportion of women participation in research.

In 1993, the National institute of health (NIH) mandated that women were to be involved in all federally funded clinical studies, unless inappropriate (Blehar et al., 2013; Mastroianni et al., 1994; National Institutes of Health, 2015). Despite this advance, women recruitment is still a problematic issue in research studies (National Institutes of Health, 2015; Schweinhart and Clayton, 2018). Further efforts are needed from researchers to identify the obstacles and barriers that can hinder participation of women in research studies. In previous studies, issues related to fetus protection, pregnancy, contraception requirement, and lack of child care have been listed as barriers against participation of women in research studies (Blehar et al., 2013; Phelan et al., 2016; Rubin, 2018; Schweinhart and Clayton, 2018; Stevens and Pletsch, 2002).

In the Middle East region and Arab countries, including Jordan, the majority of the population carry cultural and religious beliefs that could negatively affect females’ participation in research studies. Some research studies could involve culturally unacceptable practices for those populations. For example, a Muslim woman must cover her body, and males other than her first-degree relatives should not observe any part of her body, other than the face and hands. Therefore, Muslim women could...
rejection participation in research studies if they have to interact with male researchers, particularly when blood sampling, withdrawal or performing physical examination are required (Al Subeh and Alzoubi, 2020). Furthermore, shyness is a common characteristic of Muslim women, and most of them will try not to discuss sensitive topics with male individuals, such as those related to sexual intercourse or menstrual cycle. Certain habits, like smoking cigarette or doing exercise in public area, are not accepted socially for females in some regions in the Middle East (Al Subeh and Alzoubi, 2020; Islam and Johnson, 2003). Therefore, researchers must sufficiently address challenges and barriers toward research studies participation of women. As a results, new practices and approaches must be implemented to guarantee acceptable women representation in research studies carried out in the Middle East countries.

In this study, the different ethical issues related to females’ participation in research studies in Jordan were investigated from the researchers’ point of view. The results of this investigation could help researchers in Middle Eastern countries in developing recommendations to enhance women participation in research, and, thus, to achieve effective representation of women in research in a way that best goes with the population cultural and religious beliefs. As most of the ethical principles and research regulations are appropriate for western societies, there is a real need to understand barrier and challenge towards women participation in research in Middle East, and work with or modify ethical guidelines and regulations to be appropriate for this population.

2. Methods

17-item opinion questionnaire was specifically designed to conduct this descriptive cross-sectional questionnaire-based survey study. The questionnaire was targeting the researchers working in medical-related schools. With the limited literature information on this topic, the questionnaire was developed, and face validated by a group of researchers with expertise in research ethic and responsible conduct of research. Then, the semi-final version of the questionnaire was pilot tested among another group of five researchers to assess content validity and asked to provide their feedback. Accordingly, several modifications were applied using an iterative process at different stages of the questionnaire development before the final versions emerged. The questionnaire was administered in the native language for people in Jordan, Arabic language.

The entire questionnaire items were closed ended. The items of the questionnaire fall under four different sections: (1) socio-demographic characteristics (5 items); (2) the general practice among researchers in studies that involve women participation (5 items); (3) the main perceived reasons and limitations associated with hiring females as research assistants (2 items); (4) the general attitudes of researchers toward major issues related to women participation in research studies (5 items). The study questionnaire was pilot tested in 10 participants to ensure quality and comprehensibility. Additionally, subjects from the pilot sample were asked to provide comments about how they understood each survey item to ensure content clarity and comprehension. Pilot samples were omitted from the final analysis. The reliability coefficient for all items of the study was > 0.65. As for validity, the study survey was face validated via review by experts in the field, including senior medical researchers, and an ethicist.

The study was approved by Institutional Review Board (IRB) of Jordan University of Science and Technology (JUST). Electronic written informed consent was obtained before the questionnaire administration by each participant. The questionnaire was designed and uploaded to SurveyPlanet®, a professional website for developing online surveys (SurveyPlanet, LLC, Los Angeles, CA). The link to the final version of the online survey was sent to JUST researchers via e-mail. Only researchers in medicine, dentistry, pharmacy, nursing, and applied medical sciences schools were targeted in this study. The survey was opened from 29 May to 18 July 2017. A reminder invitation for the participation was sent weekly to enhance the response rate, and only those who admitted that they are researchers were allowed to access the survey. The survey was completely anonymous, and no one would be able to link the participants identity with their respective responses.

The researcher used G*Power software version 3.1.9.7 to calculate the sample size. A 0.05 significance level, a power of 0.80, and a medium effect size of 0.35 required the minimum number of subjects to be 136. The total number of study subject was 144. The Statistical Package for Social Sciences, version 22 (IBM SPSS® Statistics for Windows; IBM Corp, Armonk, New York, USA) was utilized for the analyses of the data collected. Frequencies and percentages were predominantly used to present and summarize the data generated through this study.

3. Results

Of the 450 faculty members in medical-related schools at JUST, who were approached via e-mail, 144 faculty members responded to the researcher-targeted survey with a corresponding response rate of 32%. Most respondents were married (85.4%), Jordanian (97.9 %), Muslims (95.8) researchers with age range between 25-50 years (79.2%) as shown in Table 1. Similar proportions of male and female researchers responded to the survey (52.1% vs. 47.9%, respectively), and 84.7% of respondents had conducted previous research studies on human.

Regarding researchers’ practice when conducting studies that involve female participants, two-third of researcher respondents said that they always preferentially consider hiring female research assistant (RA) to deal with those participants, while one-third of researchers said that they may consider this sometimes. Only small proportion of researchers (3.5%) will not take care of this point. According to most researchers, female RA should preferably join the research team if the study requires performing clinical examination to female participants (86.7%), conducting interview to discuss sensitive topic (86.0%), filling a questionnaire about sensitive topic (81.1%), or performing physical exercise sessions (74.1%). In general, more than half of the researchers believe that a female RA should be preferably hired in studies that require direct contact with female participants (Table 2). In the same context, large proportion of researchers believed that females in Jordanian society are less likely to participate in studies that require participants to stay outside home overnight (87.5%), to perform physical exercise (72.2%) or to smoke cigarette or waterpipe in non-private room at the research center (68.8%). In research studies that require participants to stay outside

| Variable                  | Researchers n (%) |
|---------------------------|-------------------|
| Age in years              |                   |
| 25–50                     | 114 (79.2)        |
| More than 50              | 30 (20.8)         |
| Gender                    |                   |
| Female                    | 69 (47.9)         |
| Male                      | 75 (52.1)         |
| Marital status            |                   |
| Single                    | 18 (12.5)         |
| Married                   | 123 (85.4)        |
| Divorced                  | 1 (0.7)           |
| Widowed                   | 2 (1.4)           |
| Nationality               |                   |
| Jordanian                 | 141 (97.9)        |
| Non-Jordanian             | 6 (4.2)           |
| Religion                  |                   |
| Islam                     | 138 (95.8)        |
| Christianity              | 6 (4.2)           |
| Other                     | 0 (0.0)           |
home overnight, the hospital followed by the clinical studies research center were believed to be the most convenient places to conduct such studies (46.5% vs. 31.9%, respectively).

Based on the point of view of researcher respondents, different reasons had been suggested to address the importance of preferably hiring female RA within the research team of studies that involve female participants as shown in Table 3. One of the main reasons was that women in Middle Eastern culture generally do not feel comfortable when talking or dealing with a stranger from the other gender (59.0%). Other reasons, which can be applied to most Arab Islamic countries where customs and traditions do not prefer females to deal with men outside the close family members. Moreover, conservative Islamic societies such as Jordan do not allow Muslim women to closely deal with foreign men except in the necessary cases. Interestingly, the majority of researcher respondents believed that basically, there is no existing barrier that could prevent the appointment of female RA within the research team (Table 3).

The general attitudes of researchers toward respecting women privacy upon conduction of research studies were promising, as 82.0% of the researchers agreed that it is a common practice among researchers in Jordan to respect the privacy of women when drawing blood samples, given injections, or performing clinical tests. A large proportion of researchers agreed that researchers should preferably hire female RA when the research involves female participants and that each participant should be asked whether he/she would prefer to deal with a male or female RA (Table 4). Finally, 31.3% of researchers disagreed that women in Jordanian society have the freedom to decide to participate in research studies, and 47.2% of researcher respondents agreed or strongly agreed that researchers had to seek the consent of female's close relatives, such

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**Table 2.** The general practices among researchers in studies that involve women participation (n = 144).

| Variable                                                                 | Researchers |
|-------------------------------------------------------------------------|-------------|
| Previous conduction of human subject research                           |             |
| Yes                                                                     | 122 (84.7)  |
| No                                                                      | 22 (15.3)   |
| If you were the PI of a human subject research, would you preferably hire a female research assistant to deal with the female participants? |             |
| Yes, I will always take care of this                                   | 96 (66.7)   |
| Yes, I may take care of this sometimes                                 | 43 (29.9)   |
| No, I will never care about this                                       | 5 (3.5)     |
| In your opinion, the researcher should preferably hire a female research assistant to deal with female participants if the research will involve: |             |
| IV or IM drug administration                                           | 76 (53.1)   |
| Blood sampling from the arm                                            | 75 (52.4)   |
| Collection of urine or feces sample                                    | 72 (50.3)   |
| Vital signs Measurement                                                | 77 (53.8)   |
| X-Ray imaging                                                          | 70 (49.0)   |
| Clinical examination                                                   | 124 (86.7)  |
| Physical exercise sessions                                             | 106 (74.1)  |
| Cigarette or waterpipe smoking sessions                               | 77 (53.8)   |
| Interview to discuss certain topic                                     | 74 (51.7)   |
| Interview to discuss sensitive topic                                   | 123 (86.0)  |
| Filling a questionnaire about certain topic                            | 46 (32.2)   |
| Filling a questionnaire about sensitive topic                           | 116 (81.1)  |
| None                                                                    | 5 (3.5)     |
| Females are more likely to decline their participation in the studies that involve: |             |
| IV or IM drug administration                                           | 56 (38.9)   |
| Blood sampling from the arm                                            | 30 (20.8)   |
| Collection of urine or feces sample                                    | 44 (30.6)   |
| Vital signs measurement                                                | 11 (7.6)    |
| X-Ray imaging                                                          | 41 (28.5)   |
| Clinical examination                                                   | 56 (38.9)   |
| Performing physical exercise in non-private room at the research center | 104 (72.2)  |
| Cigarette or waterpipe smoking in non-private room at the research center | 99 (68.8)   |
| Staying outside home overnight                                         | 126 (87.5)  |
| Audio-recorded discussion session                                       | 36 (25.0)   |
| Audiovisual-recorded discussion session                                | 84 (58.3)   |
| Interview to discuss certain topic                                     | 21 (14.6)   |
| Filling a questionnaire about certain topic                            | 10 (6.9)    |
| Filling a questionnaire about sensitive topic                           | 66 (45.8)   |
| None                                                                    | 7 (4.9)     |
| If you were conducting a research study that requires participants to stay outside home, what is the most convenient place to conduct this study: |             |
| Research center for clinical studies                                    | 46 (31.9)   |
| Hospital                                                                | 67 (46.5)   |
| Primary health center                                                   | 2 (1.4)     |
| No specific place                                                       | 29 (20.1)   |
as her father, husband, brother, or other family member upon her participation in research studies.

4. Discussion

Current results showed that majority of researcher will consider hiring a female research assistant to deal with female participants in research studies involving human subjects. This was particularly true when the study involved performing clinical examination, conducting interviews to discuss sensitive topic, filling a questionnaire about sensitive topic, or performing physical exercise sessions. Reasons for this practice among researcher were as follows. Firstly, the fact that women in Middle Eastern culture generally do not feel comfortable when talking or dealing stranger men. Secondly, which can be applied to most Arab Islamic countries where customs and traditions do not prefer females to deal with stranger men. Moreover, conservative Islamic societies such as Jordan do not allow Muslim women to closely deal with stranger men except in the necessary cases. In accordance, it has been recently shown that majority of potential female research participants in Jordan generally tend to avoid the participation in research studies that require discussion of sensitive issues or direct contact with participants, and in case of participation, they would prefer to deal with female research assistants (Al Subeh and Alzoubi, 2020). Moreover, Arab Muslim mothers have been reported in previous studies to express concerns about being alone with male researchers during studies-related interview (Aroian et al., 2006; Purnell, 2013). Researchers trust level, which is a major factor for participation in research studies, was shown to be lower among women and minorities (National Institutes of Health, 2015). Thus, appointing data collectors and research assistants who can establish culturally appropriate and personal relationships with participants of the study is crucial to gain their trust. This strategy was highly recommended for success in recruiting Arab Muslim mothers in research studies (Aroian et al., 2006). Interestingly, the majority of researcher respondents in the current study believed that there is no existing reason that could prevent the appointment of female RA within the research team. This is in concordance with the fact that majority of researchers reported that they will prefer to hire a female research assistant to deal with the female participants during studies involving human subjects.

Another concern that impacts participation rate of females in research studies could be the common cultural norms among Jordanian families where it is generally not acceptable for women to stay outside their homes overnight in the absence of a reasonable cause. Otherwise, the woman and her family would be stigmatized. Researchers in the current study realized that and indicated that females are less likely to participate in studies that require participants to stay outside home overnight. They further have chosen the hospital rather than the research center for clinical studies involving overnight stay of females. This again is a culturally acceptable choice where are expected to spend nights in hospital to receive treatment. This was also in agreement with our previous study where a majority of potential female research considered chosen the hospital as the most convenient place to conduct clinical research studies (Al Subeh and Alzoubi, 2020). Other chosen reasons that researcher believed could lead to lower participation of women in research where studies that involved performing physical exercise or smoking tobacco variants in non-private room at the research center,

| Variable                                                                 | Researchers |
|-------------------------------------------------------------------------|-------------|
| Why the researcher has to preferably appoint female RA to deal with female participants? |             |
| Because women in general do not feel comfortable when talking or dealing with a strange man | 85 (59.0)   |
| Because females in Jordanian society are shy and avoid the close contact with foreign men | 69 (47.9)   |
| Because customs and traditions in Jordanian society do not allow females to deal with foreign men | 76 (52.8)   |
| Because Jordanian society is a conservative Islamic society that does not allow Muslim women to deal closely with foreign men except in the necessary cases | 74 (51.4)   |
| Other                                                                   | 6 (4.2)     |
| The suggested reasons that may hinder the appointment of female research assistants within the research team |             |
| Increase the financial costs of the research                            | 17 (11.8)   |
| Difficulty of finding female RA who have the required skills to work in research | 21 (14.6)   |
| Difficulty of finding female RA who have good communication skills with others | 13 (9.0)    |
| Female RA usually face a difficulty in working with other research team members | 12 (8.3)    |
| There is no existing reason that could prevent the appointment of female RA | 108 (75.0)  |

Table 3. Main reasons and limitations associated with hiring females as a research assistants (n = 144).

| Attitudinal statement                                                                 | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree |
|--------------------------------------------------------------------------------------|----------------|-------|---------|----------|------------------|
| It is common practice among researchers to respect the privacy of women when drawing blood samples, given injections, or performing clinical examination | 47 (32.6)      | 72 (50.0) | 17 (11.8) | 8 (5.6) | 0 (0.0)          |
| In general, researchers usually hire female RA when the research involves female participants | 43 (29.9)      | 62 (43.1) | 30 (20.8) | 9 (6.3) | 0 (0.0)          |
| In research studies that require direct contact with the participants, each participant should be asked whether he/she would like to deal with a male or female RA | 60 (41.7)      | 59 (41.0) | 11 (7.6) | 13 (9.0) | 1 (0.7)          |
| Women in Jordanian society have the freedom to decide to participate in research studies without reference to anyone | 15 (10.4)      | 44 (30.6) | 40 (27.8) | 41 (28.5) | 4 (2.8)          |
| In Jordan, when researcher takes the consent of female participant, he may also have to take the consent of her guardian, such as the father, husband, brother, or other family member | 20 (13.9)      | 48 (33.3) | 31 (21.5) | 34 (23.6) | 11 (7.6)         |
which is concordance with the views of the potential research participants from the same population (Al Subeh and Alzoubi, 2020).

The general attitudes of researchers toward respecting women privacy upon conduction of research studies were positive, as vast majority indicated that they would respect the privacy of women when drawing blood samples, administered injections, or performing clinical tests. Yet, about 31% of them believed that females in Jordanian society do not have the freedom to decide to participate in research studies. They further indicated that researchers had to seek the consent of female’s close relatives, such as her father, husband, brother, or other family members upon her participation in research studies. Although the general term of “research studies” was used in the questionnaire, we think that the respondents’ opinion was related to clinical studies participation rather than survey-type studies.

As the case in most societies of Islamic and Arab countries, Jordanian people have their own cultural/religious norms and beliefs that researchers should respect. Strong family ties are the norm among members of the family of Jordan. Younger Family members must respect other family members who are older. Elder family members, on the other hand, are expected to be protective toward family members who are younger. As the culture dictates, male family members should protect and care for female family members. The father or the husband, who are usually the head of the household, must take care of his wife, mother, and daughters. Men in the Middle Eastern culture are typically the household heads and decide for other family members on permissible or acceptable activities and behaviors. Women are expected to consult the household’s head before they make decisions that are important for their life, such as applying for job, marriage, or even staying outside the home. Study findings suggest the need for special consideration in research conducted in countries with largely Middle Eastern cultures when the aim the study is largely females. In a previous study from Jordan, majority of women (69.1%) believed that females in Jordan do not have full autonomy regarding their decision to participate in research studies (Al Subeh and Alzoubi, 2020). As well, a previous study from Egypt reported that 90% of men in Egypt agreed that they have the final word about decision at home should be for the man (El Feki, Heilman and Barker, 2017). In a study from Qatar, women potential research participants asked to consult their husbands before deciding on the participation in a research study that involved an interview (Killawi et al., 2014). Hispanic women attributed a high rate of refusal among them to participate in clinical study to some of their husbands forbidding them from participation (Daunt, 2003; Martin et al., 2013). Therefore, it is apparent that in certain cultures, researchers may need to have the consent the husband, father, or brother, in addition to the consent of the female participants, when trying to recruit women as research subjects for clinical research studies.

It is important to note that women should have equal chances to be recruited as research assistants for all research studies, and in fact, this is the case of Jordan. Now, as the aim of the current study was investigating ethical issues related to women participation in research studies from researchers’ perspective, a concentration was put on the point whether women research assistants should have preferred hiring in research studies that involve women as research participants. In that respect, in countries with conservative cultural and religious beliefs, women are not expected and in fact, do not usually prefer to deal with research assistants from different gender when it comes to research studies that involve physical interaction, discussion of sensitive topics, private interviews or extended stay out of home. Thus, researchers are expected to be considered for social, and cultural beliefs/norms of study participants, and where recruiting a female research assistant would be preferred over male research assistant. Now, the current study results showed that majority of the researchers (66.7%) indicated that they will always consider a preferable hiring a female research assistant when the study involves female participants, especially when the study protocol involves direct contact with participant. Thus, this study is in fact promoting increased recruitment of women as compared to males’ counter parts.

The current study has a number of limitations. This study was carried out among researcher in only one institution, ye it is a major institution in the country. Another limitation is the relatively low response rate of 32%. Yet, such response rate is expected considering that study participants were approached via e-mail. The other limitation is the fact that the actual study was carried out back in 2017, well before COVID-19 related changes have impacted the way research is conducted. Thus, relying more on online participation. However, when it comes to clinical/medical studies, in-person close interaction is must for clinical samples, medical procedures, and diagnostic tests.

5. Conclusions

According to this study findings, it is apparent that researchers in Jordan are considerable to cultural and religious norms, where women in Jordan culture generally favor dealing with female research assistants when they participate in research studies. Researchers not familiar with norms of the culture are encouraged to consider the discussed barriers in the current study in order to increase the likelihood female participants in their research.

Declarations

Author contribution statement

Zeinab Y. Al subeh: Conceived and designed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Karem H. Alzoubi: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Wrote the paper.

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Data availability statement

Data will be made available on request.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

References

ACOG, 2015. Ethical considerations for including women as research participants. Committee Opinion No. 646. American College of Obstetricians and Gynecologists (ACOG). Obstet. Gynecol. 126, e100–e107.
Al Subeh, Z.Y., Alzoubi, K.H., 2020. Cultural and religious barriers influencing the participation of women in research: a study from Jordan. Gend. Issues 37 (2), 173–186.
Aroian, K.J., Katz, A., Kulwicki, A., 2006. Recruiting and retaining Arab Muslim mothers and children for research. J. Nurs. Scholarsh. 38 (3), 255–261.
Beanchamp, T.L., Childress, J.F., 2016. Principles of Biomedical Ethics. Bird, C.E., Rieker, P.P., 1998. Gender matters: an integrated model for understanding men’s and women’s health. Soc. Sci. Med. 48 (6), 745–755 (Print).
Blehmar, M.C., Clayton, J.A., Spong, C., Grady, C., Goldkind, S.F., Sahin, L., 2013. Enrolling pregnant women: issues in clinical research. Women’s Health Issue 23 (1), e39–e45.
Duant, D.J., 2003. Ethnicity and recruitment rates in clinical research studies. Appl. Nurs. Res. 16 (3), 189–195.
El Feki, S., Heilman, B., Barker, G., 2017. Understanding Masculinities: Results from the International Men and Gender Equality Survey (IMAGES) – Middle East and North Africa. UN Women and Promundo US.
Islam, S.M.S., Johnson, C.A., 2003. Correlates of smoking behavior among Muslim Arab-American adolescents. Ethn. Health 8 (4), 319–337.

Killawi, A., Thurston, M., Fetters, M.D., Khidir, A., Elnashar, M., Abdelrahim, H., Al-Khal, A.L., 2014. Procedures of recruiting, obtaining informed consent, and compensating research participants in Qatar: findings from a qualitative investigation. BMC Med. Ethics 15 (1).

Kwiatkowski, K., Coe, K., Ballar, J.C., Swanson, G.M., 2013. Inclusion of minorities and women in cancer clinical trials, a decade later: have we improved? Cancer 119 (16), 2956–2963.

Martin, A., Negron, R., Bailbierz, A., Bickell, N., Howell, E.A., 2013. Recruitment of black and Latina women to a randomized controlled trial. J. Health Care Poor Underserved 24 (3), 1102–1114.

Mastroianni, A.C., Faden, R.R., Federman, D.D., 1994. NIH revitalization act of 1993 public law 103-43. In: Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies, vol. I. National Academy Press, Washington, D.C.

National Institutes of Health, 2015. Consideration of Sex as a Biological Variable in NIH-Funded Research. Notice Number: NOT-OD-15-102. https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html. (Accessed 17 May 2019).

Phelan, A.L., Kunselman, A.R., Chuang, C.H., Raja-Khan, N.T., Legro, R.S., 2016. Exclusion of women of childbearing potential in clinical trials of type 2 diabetes medications: a review of protocol-based barriers to enrollment. Diabetes Care 39 (6), 1004-1009.

Purnell, L.D., 2013. Transcultural Health Care : a Culturally Competent Approach. F. A. Davis, Philadelphia.

Rubin, R., 2018. Addressing barriers to inclusion of pregnant women in clinical trials. J. Am. Med. Assoc. 320 (8), 742-744.

Schweinhart, A., Clayton, J.A., 2018. Reversing the trends toward shorter lives and poorer health for U.S. Women: a call for innovative interdisciplinary research. Int. J. Environ. Res. Publ. Health 15 (9), 1796.

Stevens, P.E., Pletsch, P.K., 2002. Informed consent and the history of inclusion of women in clinical research. Health Care Women Int. 23 (8), 809-819.

van der Graaf, R., van der Zande, I.S.E., den Ruijter, H.M., Oudijk, M.A., van Delden, J.J.M., Oude Rengerink, K., Groenwold, R.H.H., 2018. Fair inclusion of pregnant women in clinical trials: an integrated scientific and ethical approach. Trials 19 (1), 78.

Vitale, C., Fini, M., Spoleini, I., Laincak, M., Seferovic, P., Rosano, G.M., 2017. Under-representation of elderly and women in clinical trials. Int. J. Cardiol. 232, 216-221.