Chapter 16

Participation in Investigational Fertility Preservation Research: A Feminist Research Ethics Approach

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Introduction

The goals and rhetoric of The Oncofertility Consortium [1] are aimed toward preserving cancer patients' reproductive choices and facilitating their reproductive autonomy after cancer. While the end goals of oncofertility research are oriented toward safeguarding the possibility of biological reproduction for women and girls facing cancer treatments that may affect their reproductive capacity, considerable basic and clinical research is still needed in order for oocyte cryopreservation, in vitro follicle maturation, and ovarian tissue cryopreservation to become established fertility preservation techniques. In fact, at the time of writing, all of the professional organizations that have published guidelines on fertility preservation techniques consider embryo cryopreservation to be the only established fertility preservation method utilizing assisted reproductive technology (ART), while oocyte and ovarian tissue cryopreservation are considered investigational or experimental techniques that should only be offered under Institutional Review Board (IRB)-approved research protocols [2–8].

The Ethics Committee of the American Society for Reproductive Medicine (ASRM) argues that additional research is needed to assess the safety and efficacy of these investigational methods in IRB-approved human trials with cancer patients [4]. Further clinical research with these patients will help to determine the optimal patient population, techniques for collecting tissue, and protocols for cryopreservation and in vitro follicle maturation [8]. In addition, human oocytes and ovarian tissue are needed in order to conduct basic research to establish the appropriate patient population, methods of tissue collection, and cryopreservation and maturation techniques that will help the oncofertility enterprise move these techniques from investigational to established methods of fertility preservation [3, 8].

From a feminist research ethics perspective, the ethical standards for conducting both basic and clinical research must include but also go beyond ensuring IRB approval of human subjects research and collating evidence of safety and efficacy. To proceed with fertility preservation research in an ethical and just manner, it is also important to ask the following: (1) on whose bodies is fertility preservation research dependant? and (2) in selecting research subject populations, how should researchers balance the risks and benefits to prospective participants? This chapter applies a feminist research ethics

approach to the oncofertility context, with a particular focus on the sources of oocytes and ovarian tissue for investigational fertility preservation research and the potential vulnerabilities of participating in this research.

Feminist Approaches to ART and Biomedical Research

As women's bodies are the site of the bulk of reproductive interventions, feminists have had a long-standing interest in ART that has evolved around the differential physical burdens that women and men experience in fertility treatments [9]. In her review of feminist literature on infertility, Charis Thompson has argued that most of the early feminist writings on ART expressed "moral certainty" that hi-tech reproduction was bad for women, but since roughly the early 1990s there has been a shift in the feminist literature toward "moral ambivalence" regarding these technologies [9]. Thompson marked a gradual shift in the feminist literature "from easy condemnations toward multiplicities of women's experiences of reproductive technologies" [9, p. 69] as responsiveness to growing claims by women using ART that these technologies enabled them to exercise reproductive choice and feminist acknowledgement that individuals have varied encounters with reproductive medicine depending on their positionality in society [10]. Despite this shift in tone, the feminist work on reproductive technologies has continued to caution that the dominant cultural narrative that normative womanhood includes and even mandates motherhood has maintained the "need" for ART, and helped it to grow, especially for some sectors of the population [9, 16–19].

An outgrowth of feminist analysis of ART has been the feminist scholarship on biomedical research that involves reproductive material. To date, these feminist analyses have primary focused on the use of embryos and oocytes for human embryonic stem cell (hESC) and somatic cell nuclear transfer (SCNT) research. Existing feminist critiques of hESC and SCNT research have been leveled at the potential risks to and commodification of women's bodies in the reproductive labor required to produce oocytes for research [9, 16, 17] and the potential for coercion of women and their partners who have spare embryos from in vitro fertilization (IVF) treatments that could be donated for research [20, 21]. Catherine Waldby has also raised concerns that the growing demand for oocytes for SCNT research has the potential to exploit already impoverished women as sources of oocytes since ART is differentially regulated globally and regulations regarding financial compensation for oocytes vary from country to country [19]. Because both IVF patients and healthy research volunteers are possible providers of oocytes for research purposes, Angela Ballantyne and Sheryl de Lacey have argued that it is important to consider the different circumstances under which each of these populations of women may come to provide oocytes for research, and that each source of oocytes requires its own research ethics guidelines to ensure just selection of participants in research involving reproductive materials [22].

Oncofertility: Patients, Basic Research, and Clinical Research

Oncofertility research sits at a crossroads between basic biomedical research and clinical research on emerging forms of ART, which makes it a particularly interesting site for

feminist analysis of research involving reproductive materials. In some ways, oncofertility research is similar to hESC and SCNT research because reproductive materials are needed for basic research on fertility preservation techniques.
In other ways, oncofertility research is more like ART research because both involve clinical research with patients who could directly benefit from the fertility techniques being "investigated" on their bodies. However, while the basic research involved in hESC and SCNT is meant to generate generalizable medical knowledge for the development of stem cell therapies for a range of medical conditions [22] and ART procedures have primarily been integrated into commercial clinical practice without prior establishment of safety and efficacy in primate models [23, 24], oncofertility research has been designed to evolve through collaboration between basic research and a systematic multi-site clinical-trial model which can yield guidelines for fertility preservation protocols specifically for cancer patients [24]. In light of these unique characteristics of oncofertility research, Laurie Zoloth has described a triple role for women and girls with cancer participating in investigational oncofertility protocols as patients, human subjects in clinical research, and tissue providers for basic research (Zoloth, this volume) This raises the question: given their triple roles as patients, tissue donors for basic research and as human subjects in clinical research, are cancer patients the most appropriate population to be participating in research on investigational fertility preservation techniques? What particular risks and vulnerabilities does this population face in these roles, and how might they be mitigated? And if this is not the most appropriate research subject population, who might be? The following section will explore these questions in depth.

Potential Participants in Investigational Fertility Preservation Research

Writing about the ethics of oocyte provision for stem cell research, Ballantyne and de Lacey have argued that a feminist research ethics framework requires careful attention to selection of research participants. They explain:

> The principle of 'just participant selection' requires that research subjects be selected from the population that stands to benefit from the research. Based on this principle, infertile women should be actively recruited to donate eggs for fertility-related research *only*. It is unethical to exclusively or predominantly recruit infertile women to donate eggs for stem cell research that concerns general medical conditions. It is preferable to recruit women from the general population to donate eggs for such research, and these women should be viewed as healthy volunteers. To avoid exploitation, these donors should receive compensation for both the direct and indirect costs associated with their donation [22, p. 145].

For the purpose of my analysis, I will consider the applicability of Ballantyne and de Lacey's framework of just research participant selection to the context of investigational fertility preservation research, with a particular focus on oocyte cryopreservation and ovarian tissue cryopreservation. Populations who have participated or who have been proposed as potential participants in investigational fertility preservation research thus far include cancer patients, fertility patients, women who are already donating oocytes for

reproduction, and healthy research volunteers providing oocytes or ovarian tissue specifically for research. Each population will be considered in turn.

Cancer Patients

Patients seeking fertility preservation in light of a cancer diagnosis may be faced with a decision regarding whether to participate in an investigational fertility preservation protocol. Currently both basic and clinical research involving ovarian tissue cryopreservation rely almost exclusively on cancer patients as research participants and sources of ovarian tissue [25]. Practice guidelines allow for up to 20% of ovarian tissue collected for fertility preservation to be allocated for basic research to improve the technique, and the rest of the ovarian tissue is cryopreserved for the patient's future reproductive use in the event that her cancer treatments result in ovarian failure [26, 27].

To apply the framework of just participant selection to fertility preservation research, it would hold that it is just to offer young women and girls who may become infertile due to cancer treatments the opportunity to participate in investigational fertility preservation research. Participation in investigational fertility preservation research, as opposed to utilizing the more established method of embryo cryopreservation, is especially justifiable if the woman or girl does not have a partner, if she would prefer not to use donor sperm to create embryos for cryopreservation, or if she does not have time to participate in IVF before commencing cancer treatment [4, 26, 28]. As feminist theorist Karey Harwood has argued, participation in investigational fertility preservation research "is more justifiable if it is the patient's last best hope to preserve normal biological function in the face of a serious illness such as cancer," [23, p. 43] and in light of the abovementioned constraints this "last best hope" makes her more likely to personally benefit from the improvement of investigational fertility preservation techniques.

Despite the appropriateness of participation by the cancer patient population in research due to the potential personal benefit, concerns have been raised about the potential vulnerabilities that this population might face. In the case of oocyte cryopreservation these concerns include delay of cancer treatment and the introduction of ovarian stimulation hormones to mature oocytes in vivo, which may exacerbate estrogen-sensitive tumors [28]. Others have raised the concern that inadequate knowledge creates the opportunity for unjustified optimism regarding outcomes of participation in clinical fertility preservation research involving investigational methods [23]. Even when the risks and limitations of experimental research are fully explained to patients, there is a possibility that participants make have a high degree of hope that they will survive the cancer and that the fertility preservation technique will work for them [6, 24, 29]. As Inmaculada de Melo-Martin and Ina N. Cholst have argued, "evidence suggests that, although some people cite altruistic motives as their reason to participate in clinical trials, self-interest – in particular, they hope to benefit from the research – is more commonly given as a reason for participating in trials" [28, p. 526]. This perception of therapeutic benefit associated with participation in investigational research may raise the potential for false hope both for fertility preservation and for cancer treatment [23, 29], but as Zoloth has argued, it would be inaccurate to characterize this as therapeutic misconception

because there is a real possibility for potential personal benefit to be gained from participation in investigational fertility preservation research (Chapter 24 by Zoloth, this volume). Clearly cancer patients' participation in fertility preservation protocols is not simply a case of altruistically motivated participation in research to advance medical knowledge if they themselves could benefit directly from the research. Striking the balance between patients' reproductive autonomy and appropriate research subject selection requires careful attention on the part of researchers recruiting participants for both basic and clinical research. Despite the fact that cancer patients are in the position to benefit most from the outcomes of research, they are vulnerable to the possibility of presuming there is a therapeutic benefit to participation in research even if the technique is still investigational. This is particularly relevant as the available investigational techniques are at different stages of technical maturity and have differential live birth rates. For instance, human live births have resulted from both oocyte cryopreservation and ovarian tissue transplantation while as of yet there have been no human live births with the use of in vitro follicle maturation techniques.

In addition, at this time little is known about long-term viability of cryopreserved human oocytes and ovarian tissue, the efficacy of using these fertility preservation techniques, and long-term health risks associated with these techniques [23, 30]. The model of enrolling those most likely to benefit from both clinical and basic research has been employed in the development of other forms of ART, but one danger of this precedent has been that investigational techniques have often moved into clinical use in the private medical sector with professionally generated practice guidelines instead of using a model of controlled clinical trials [24]. Thus it will be particularly important for clinicians and basic researchers involved in enrolling cancer patients in their investigational research protocols to ensure that these techniques are monitored for safety, efficacy, and long-term health outcomes of participants and any resulting children before they are deemed established methods in the realm of fertility preservation.

Fertility Patients

For many women seeking fertility treatment, the goal of having a genetically related child is paramount. Women experiencing infertility may benefit from investigational fertility preservation research since it may offer more reproductive options to women who are seeking assistance with conception. Facilitating patients' reproductive choices has been a primary goal of assisted reproductive medicine in the United States (US), but it is important to assess whether and how fertility patients' reproductive autonomy is preserved and/or compromised through participation in investigational fertility preservation research. The ethical permissibility of participation in elective oocyte or ovarian tissue cryopreservation – both investigational techniques – to delay childbearing for social or lifestyle reasons has been addressed extensively in the literature [23, 28, 31, 32]. Thus rather than reiterating the debate on fertility preservation for lifestyle reasons here, my analysis will focus on women currently seeking treatment for infertility.

The ASRM has issued guidelines indicating that if IVF patients have oocytes that they are not going to utilize for their own fertility treatments, it is acceptable for these tissues

to be donated for research provided that the patients undergo informed consent, that the decision to donate oocytes to research is not coerced, that the decision is separate from the decision to continue or terminate fertility treatment, and that patients are aware that they will not personally benefit from the outcome of the basic research [33]. Basic fertility research has relied on the donation of oocytes from IVF patients to improve upon oocyte cryopreservation and in vitro oocyte maturation techniques [34, 35], and following Ballantyne and de Lacey's framework, the participation of this population in basic fertility preservation research is justified since the population experiencing infertility stands to benefit from fertility-related research. However, due to the reality that fertility patients may have age-related diminished ovarian reserve and the immediacy of the fertility problems that women seeking fertility treatments are facing, it would be unjust to solicit the participation of IVF patients for basic ovarian tissue cryopreservation research because they themselves could experience more harm than benefit to their reproductive health and reproductive goals from removal of ovarian tissue for basic research purposes.

As for clinical research, the question remains as to whether it would be just to enroll women currently seeking fertility treatments in investigational fertility preservation research protocols such as oocyte or ovarian tissue cryopreservation. These investigational fertility preservation techniques are designed with the idea that a woman or girl's reproductive genetic material may be cryopreserved for use at a future date, while fertility patients may already be embroiled in the physical and emotional rigors seeking more immediate resolution to their fertility problems with ART. Given these temporal constraints and the immediacy of fertility patients' desires to build a family, de Melo-Martin and Cholst have argued that it would be more appropriate to utilize established fertility treatment protocols with this population because these women may already have compromised fertility and more established methods of fertility treatment would be more likely to help them to achieve their goal of having a baby than would an investigational technique [28]. However, they have also argued that it would be just to enroll current fertility patients in investigational research on fertility techniques only if other more established options had been excluded for moral, religious, or logistical reasons [28]. This option might be particularly relevant for women who are opposed to the creation and cryopreservation of embryos for future use, but would be willing to participate in ovarian stimulation and oocyte harvesting with the intention of only fertilizing the number of oocytes that could be transferred for pregnancy at one time or if they would be willing to use cryopreserved donor oocytes for their own fertility treatments [28].

Despite the fact that fertility patients as a population may benefit from the eventual maturation of cryopreservation techniques for oocytes and ovarian tissue, due to the immediacy of fertility patients' desires to conceive and have a baby, this is not the ideal population for participation in clinical fertility preservation research. Direct benefit may be less likely and could raise the potential for eliciting false hope for its immediate success. Despite any moral ambivalence that feminists may have regarding ART, it is ethically imperative that women who are willing to undergo the physical and emotional burdens of fertility treatment be best positioned to benefit from their efforts. However,

investigational fertility preservation research is not necessarily the most well matched to achieving their reproductive goals at the present time.

Reproductive Oocyte Donors

It has also been suggested in the scientific and bioethics literatures that women already donating oocytes for reproductive purposes might be an appropriate population to donate oocytes for basic and clinical fertility preservation research [28, 36]. While the Centers for Disease Control and Prevention reported that donor oocytes were used in approximately 13.7% of all IVF cycles in the US in 2005 (14,646 cycles overall) [37], egg-sharing arrangements, which are characterized by the donation of some of the oocytes from a donation cycle to researchers are not common in the US. In the United Kingdom, the Human Fertilization and Embryology Authority allows IVF patients to enter into egg sharing for research purposes [38], but in the US women who are providing oocytes for another woman to use to try to have a baby are not typically involved in egg sharing with researchers.

While not uncontroversial, women who are reproductive oocyte donors have already taken on the risks associated with ovarian stimulation and oocyte harvesting to donate oocytes for reproductive purposes. Given that they have already undertaken the risks associated with oocyte donation, these women may be an appropriate population to provide oocytes for fertility-related research even if they themselves would not personally benefit from fertility preservation research [28]. However, because they will not benefit directly from fertility preservation research, egg sharers would be more appropriately categorized as healthy research volunteers. Applying Ballantyne and de Lacey's framework of just selection of research participants, it would be just to enroll egg sharers in basic fertility preservation research if they provide informed consent and they are adequately compensated for the direct and indirect costs associated with their participation in the research.

At face value this may seem straightforward. However, there are potential pitfalls associated with the informed consent process, knowledge of disposition of oocytes and the potential for commodification when enrolling egg sharers as healthy research volunteers. While it is standard practice for oocyte donors to relinquish property rights to their oocytes once they have provided informed consent for their extraction and donation [17], consent forms for reproductive oocyte donation have not always disclosed that donated oocytes and embryos resulting from the donated oocytes might also be frozen, discarded, or donated for research or to another couple for fertility treatments [39]. Previous research involving reproductive oocyte donors indicates that donors may have varying degrees of comfort with donating their oocytes for research purposes [40, 41], thus it is especially important to ensure that women considering egg sharing arrangements are apprised of the nature of fertility preservation research in the informed consent process. Similarly to IVF patients donating oocytes to research, it is important that egg sharers provide adequate informed consent for their participation in investigational fertility preservation research and that their decision is not make under undue influence [33]. In addition, applying Waldby's concerns regarding stratified oocyte

markets to the context of fertility preservation research [19], the potential for exploitative commodification of oocytes in egg sharing arrangements runs high, particularly if they result in differential compensation for oocytes than reproductive oocyte donation or donation of oocytes specifically for research. While egg sharing arrangements for research may be justified under specific guidelines for informed consent and compensation, there is potential that this population may face similar risks to their health and commodification or exploitation of their reproductive resources as the population of healthy research volunteers discussed below.

Healthy Research Volunteers

The final category to consider for participation in investigational fertility preservation research is the population of healthy research volunteers. This population consists of healthy women willing to provide oocytes and ovarian tissue expressly for basic fertility preservation research. These individuals do not stand to benefit directly from the knowledge generated from investigational fertility preservation techniques, therefore according to Ballantyne and de Lacey's framework for just selection of research participants, just participation would necessitate the provision of informed consent and compensation for the direct and indirect costs associated with participation.

Ballantyne and de Lacey assert that adequate compensation for involvement in research can help avoid exploitation of healthy research volunteers, but the potential for exploitation still exists, particularly when differential compensation schemes and volunteers' long-term health are considered. The solicitation of healthy research volunteers to provide oocytes for stem cell research can serve as an instructive model for the fertility preservation research context. In the US context the stem cell community has solicited healthy young women to donate oocytes specifically for research purposes, but leading stem cell researchers have been unsuccessful in their efforts due to inadequate compensation schemes for research volunteers [42]. However, private oocyte donation companies and New York State's new allowance for financial compensation for oocyte donation specifically for research may offer the opportunity to assess women's willingness to participate when both direct and indirect costs are covered at rates comparable to women providing oocytes for reproductive purposes [19, 43]. Researchers' experience of offering inadequate compensation to prospective donors suggests that compensation is an important factor in the decision-making process for prospective healthy research volunteers for stem cell research which would imply that the same may be true for fertility preservation research volunteers. Given the importance of compensation for participation in research, it is important to raise Waldby's concern that stratified payment for reproductive tissues exacerbates the potential for exploitation of poor women seeking to reap financial rewards for providing their scarce reproductive resources to researchers [19]. Should fertility preservation researchers seek healthy research volunteers to provide oocytes and ovarian tissue, guidelines would be needed to ensure measures for achieving fair compensation without financial exploitation.

Another population of healthy research volunteers who may provide oocytes or ovarian tissue for fertility preservation research would be women undergoing voluntary

sterilization [31] or who have had undergone elective oophorectomy for other medical reasons [25]. These populations have donated reproductive tissues for other types of fertility-related research [44], thus it may be appropriate to involve their participation in fertility preservation research. However, the decision to undergo sterilization or have an ovary removed would necessarily need to be separated from the decision to donate oocytes or ovarian tissue for fertility preservation research, and undue inducement in the form of financial or other compensation would need to be prohibited. Careful consideration is needed to establish protocols for adequate compensation in relation to related risks of participation for this population.

The main vulnerability that the participation of healthy research volunteers elicits is related to the long-term health implications of ovarian stimulation and ovarian tissue removal. Ovarian tissue removal and oophorectomy have well-characterized risks related to undergoing a surgical procedure as well as reproductive health risks such as surgical menopause [45]. And although there has been speculation on links between ovarian stimulation and long-term health risks like ovarian, endometrial, and breast cancers, ovarian cysts, fibroids, thyroid disorders, and pelvic pain, the results of existing research has been inconsistent in drawing causal links between ovarian stimulation and these health risks [46–49]. Given the particular commitment of oncofertility research to protecting the reproductive potential of cancer patients, additional research is indicated to assess the long-term health risks of oocyte donation and ovarian tissue donation both for reproductive and research purposes. Presently it is unknown whether the involvement of healthy research volunteers in fertility preservation research may put volunteers' own fertility and reproductive health at risk. For this reason, it would be advisable to focus investigational fertility preservation research on populations most likely to benefit from the clinical outcomes of research rather than to jeopardize healthy research volunteers' reproductive health.

Conclusions and Directions for Future Research

While there are potential pitfalls associated with each of these prospective research populations, cancer patients are the most appropriate population to participate in both basic and clinical investigational fertility preservation research because they are most likely population to benefit from the establishment of these methods in clinical care. Fertility patients, reproductive oocyte donors, and healthy research volunteers may be suitable research subject populations for the basic research associated with investigational fertility preservation techniques under certain circumstances, but the potential risks to their own reproductive health and the potential for commodification of their reproductive tissues make these populations more vulnerable as research subject populations than women facing fertility-limiting cancer treatments. Hence, women whose cancer treatments are likely to adversely affect their fertility should be the primary population recruited for participation in investigational fertility preservation research.

Finally, while facilitating patients' reproductive autonomy is paramount, it is important to raise the longstanding feminist question regarding ART of whether the existence of

investigational fertility preservation techniques raises the technological imperative to participate [9, 11–15]. Querying which cancer patients will be most likely to participate in investigational fertility preservation research, and if and how the decision to participate relates to a cultural norm of achieving womanhood through biological motherhood will be important directions for future research. To this end, adequate assessment of the ethical implications of investigational fertility preservation protocols should include the perspectives of those women and girls who have considered and participated in investigation fertility preservation research. At this time little is known about patient receptiveness and enthusiasm for various fertility preservation methods and what factors impact patients' decisions to choose an established method, an investigational method of fertility preservation or to forego fertility preservation with ART. Results from a preliminary study reviewing cancer patients' charts in a fertility preservation program revealed that more patients opted for the established method of embryo cryopreservation or opted out of ART-assisted fertility preservation altogether than chose either oocyte cryopreservation or ovarian tissue cryopreservation [25]. Hence, it is important to systematically track cancer patients' motivations for choosing specific fertility preservation techniques and their attitudes about use of reproductive tissues in basic fertility preservation research, as well as to include long-term follow up with women and girls who opt in and opt out of fertility preservation research. Further exploration of the experience of participation in fertility preservation research will provide important insight into the worldviews and moral frameworks of those poised to benefit from investigational fertility preservation techniques, which will in turn provide firmer ground for empirical bioethical analysis of the risks and benefits of participation in investigational research.

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