Chapter 14
Contested Tissues: The Donation of Oocytes and Embryos in the IVF-Stem Cell Interface in China

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14.1 Introduction

Human embryonic stem cell research has been a rapidly growing area within the life sciences since their discovery in 1998 (Thomson et al. 1998). A fundamental prerequisite for human embryonic stem cell (hESC) research is the sourcing of human embryos. The supply of embryos is made possible by the in vitro fertilization (IVF) of oocytes as part of infertility treatments, a process that routinely involves the creation of larger numbers of embryos. Depending on national regulations, "surplus" or "spare" embryos that IVF patients do not plan to use for reproductive purposes can be donated for stem cell research. In the laboratory, the inner cell mass of the donated embryos is isolated, modified, and cultured to colonies of hESC. These "spare" embryos are typically donated through a system of voluntary gifting, which is based on informed consent. The IVF clinic is thus the pivotal point in a triangular relationship that links the stem cell laboratory with the donors of the "biological raw material" on which stem cell economies rely: women and couples undergoing IVF treatment. Sarah Franklin has called this relational space the "IVF-stem cell interface" (Franklin 2006, p. 86). The need of hESC for stem cell research has confronted IVF patients with new choices and moral dilemmas, and it has led to a conflict of interests between the needs of patients and the requirements of the research lab. IVF clinicians are between these two interests and faced with the difficult task to balance the professional codes of the clinic with the demands of research (Svendsen and Koch 2008, p. 94). This situation is particularly demanding when IVF clinicians are also stem cell researchers or when a stem cell lab is part of (or part of the same institution as) an IVF clinic, which is often the case.

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During 3 months of ethnographic field research in China, conducted between 2008 and 2009, I followed the pathway of human reproductive tissues (human gametes and embryos) on their way out of the human body into the IVF clinic and then from the clinic into the stem cell research laboratory. As I have illustrated elsewhere (Rosemann 2011, 2016, under review), this journey is paralleled by the systematic reconceptualization of the value, the status, and the meanings ascribed to these tissues. While initially intimately entangled with the physical, emotional, and social realities of their biological originators, in the course of the donation process, these bonds are gradually disconnected, and the telos and biological significance of these tissues is redefined (Waldby and Mitchell 2006). These changes enable and legitimize the destruction of human embryos and their transformation to hESC lines and use for scientific research. These changes enable, furthermore, the integration of these lines into new relational networks and systems of exchange, including their exchange as a commodity (Waldby and Mitchell 2006).

This chapter focuses on value conceptions of embryos and donation practices in the context of the IVF clinic, with a particular focus on the enactment of informed consent procedures. A question that I ask in this respect is what ideas are communicated to potential embryo donors, so that the donation of their spare embryos for hESC research appears reasonable and justifiable. The structure of this paper is as follows. I will first explore the role and meaning of informed consent procedures and the attitudes on informed consent among IVF clinicians from five IVF clinics in China. I will then examine actual donation practices. I will focus in particular on the more problematic aspects of embryo donation, which involve the provision of false facts and forms of rhetoric deception. I will then discuss these findings with regard to the regulatory context in which hESC are donated, banked, and distributed to researchers. I will draw, in this regard, on a comparison with the UK and in particular the role of the UK stem cell bank. First, however, I will provide some information on the methodology of this study.

14.2 Methods

The data presented in this chapter were gathered in China in February and March 2008 as well as August 2009. In this time, I visited five IVF clinics and six stem cell centers in three cities in Southeast and Central China. Research methods comprised the analyses of documents, semi-structured open-ended interviews with 15 stem cell scientists, 15 IVF clinicians, and 15 embryo donors, as well as a quantitative survey study whose findings are presented elsewhere (Rosemann 2010; Rosemann 2016, under review). The names of researchers and clinicians that are cited in this article have been anonymized.

14.3 Informed Consent: Purposes and Attitudes

Informed consent (IC) is commonly portrayed as an indispensable bioethical principle that safeguards autonomy and protects the patients' right to take a fully informed decision (Corrigan 2003, p. 768). An alternative way of defining the role and functions of IC procedures has been proposed by Waldby and Mitchell (2006). Instead of looking at informed consent as a mechanism to protect patient rights, they analyze it as a mechanism for the protection of the interests of clinicians and researchers. The signing of a consent form, the authors suggest, relocates the rights of ownership from donors to researchers. This step encompasses the renouncement of all legal claims to the results, benefits, and profits that might be derived through the use of the donated embryo (Waldby and Mitchell 2006, pp. 71–73). This view was fully confirmed in the context of my research. As the following two quotations show, clinicians and researchers experience informed consent as a crucial safeguard for the protection of their activities and interests.

> Senior IVF clinician 1: For donation [after a treatment] patients must come back to here, personally and sign the consent form. Otherwise, several years later, a patient might say: "Where is my embryo?" No, this is impossible!
>
> I: That means the consent form is also a kind of a contract, a legal document that protects the clinic?
>
> Senior IVF clinician 1: Yes. It is very important … for both doctors and the patients. [It] is very important to protect the doctor! Otherwise it is terrible. It may be a disaster to a center.
>
> Senior IVF clinician 2: All details are literally stated there. Once a patient has signed a paper, for the researchers or doctors it is very safe, very safe.
>
> I: Very safe, why precisely?
>
> Senior IVF clinician 2: We have a paper here, a signature. We have a consent paper signed by the patient; of course, it is safe now for the technician to use the embryo.

Importantly, from the perspective of the donor, signing a consent form means they abstain from all rights to access to both medical and financial benefits that might be achieved through the act of donation:

> Senior IVF clinician 3: [It is specified here that] patients cannot achieve any kind of economic goods from a [developed] treatment.
>
> Senior IVF clinician and stem cell researcher 1: If you sign the informed consent form, you have to agree that you really have no rights to the medical benefits of the research. I know that because I am [besides my work as clinician] also involved in a research programme. It is said there that you will not get any benefits from the things we do. In my personal opinion I think that is not fair.

In my interviews, most of the IVF clinicians and researchers with whom I spoke expressed a well-developed responsibility awareness of the needs and concerns of patients. In particular, senior IVF clinicians endorsed the requirement to stick to ethical principles such as informed consent and the right of IVF patients for a voluntary and autonomous decision:

> Senior IVF clinician 4: They [the patients] have the right ... their behavior is totally voluntary, not under any pressure from the researchers or the doctors and [...] no matter how they will decide, their clinical treatment will not be influenced at all.
>
> Senior IVF clinician 5: We have to explain to them, we have to offer different options, and then the patients make a decision by themselves.
>
> Senior IVF clinician and stem cell researcher 2: We have to protect the rights of patients, so that they receive all the embryos they need for a successful pregnancy. Then we have to give information to donors about our research [...]. We have to inform patients, also if we want their low-quality embryos.

Many more examples could have been provided here. It is important to note, however, that the overwhelming majority of these statements come from clinicians and stem cell researchers in senior organizational functions who would only sporadically conduct informed consent procedures themselves. It is not surprising that at the level of actual practice, a more varied picture emerged.

14.4 Informed Consent and Actual Donation Practices

For persons who undergo infertility treatment, the in vitro generated embryo signifies a source of profound hope and value. After the diagnosis and yearlong experience of infertility, the creation of these embryos constitutes an important source of "reproductive capital." The IVF embryo, in other words, embodies the promise to render a long-cherished but recurrently frustrated wish to have one's own child into the realm of the possible. However, whatever the initial ideas among infertility patients on their embryos may have been, in the course of the IVF treatment, these conceptions and feelings are subjected to considerable changes. IVF patients are exposed to new forms of expertise and explanations, and the embryos that are created in the laboratory are subjected to rigorous testing of their quality, morphology, and reproductive viability. In other words, in the context of their treatments, patients learn to think about the characteristics and value of their embryos through the technical categories and quality parameters of the IVF space. This process can give rise to disappointments and a significant "culture shock" among laypeople. This restructuring of ideas, attitudes, and mental images of patients' embryos does clearly facilitate the attempts of clinicians or stem cell researchers to motivate IVF patients to donate their spare embryos for research. An important reason for this is that IVF embryos are evaluated and categorized along parameters of reproductive potentiality, which means that some embryos are defined as being of lower reproductive value than others. Another reason is that the explanations and quality categories of the IVF clinic enable the overcoming of alternative understandings of life, value, ethics, and sociality, such as defined by common sense, tradition, or religion. While I have discussed some of these points elsewhere (Rosemann 2016, under review), I shall provide a number of examples that offer insights into the ways in which the donation of embryonic tissues is carried out in the IVF clinics I visited.

14.4.1 Exploring Clinical Practices: Disparities Between the Real and Projected Value of hESC

A key finding from my research was that there exist some fundamental contradictions between the value descriptions of donated embryos as conveyed by IVF clinicians to IVF patients in the context of the donation procedure and the ways in which potential benefits from hESC can be used in the future. These disparities between "projected" and "real" value refer to a critical power imbalance between embryo donors and IVF clinicians as well as stem cell researchers. This situation opens up fundamental questions regarding benefit sharing and justice (see also Dickenson 2006; Waldby and Mitchell 2006; Sleeboom-Faulkner 2014).

Communication practices and the ways in which the donation process of human embryos for hESC research were conducted varied considerably between but also within the different clinics I visited. The majority of IVF clinicians with whom I spoke expressed a well-developed responsibility awareness of the needs and the moral dilemmas of IVF patients. These clinicians and researchers stated that they do their utmost in informing patients, in answering their questions, and in offering time to discuss donation with friends or family. However, more problematic aspects could be observed. Some IVF clinicians would carry out IC procedures in a less mindful manner and in ways that violated the interests of patients and their right to receive complete and unbiased information. As the following example shows, ideas such as "the right to be informed" were sometimes handled in superficial and rather unsatisfactory ways:

> I: When you ask patients to donate their low-quality embryos for hESC research, what information do you provide to them?
>
> Junior IVF clinician 1: Information? (Laughs) ... Not much information. Just these words written down on this paper here, not much more information. [She points to a multiple-purpose informed consent form that lies on the table in front of her, which has to be filled in and signed before the onset of the treatment; most of the issues that were covered here refer to the risks and procedures of the infertility treatment itself; the donation of low-quality embryos for hESC research was only one issue among many, and dealt with in two sentences. It is specified that the donated embryos shall be used for research and that they will be destroyed in the process and cannot be reclaimed.]
>
> I: But the woman [an IVF patient] we spoke to this morning, she didn't know anything about stem cell research. Don't you have to explain it to her?
>
> Junior IVF clinician 1: It is just a brief, a brief explanation. It doesn't have many details.
>
> I: But does that happen often that a woman is asked to sign a form and she does not really know what for? I mean, for what kind of research the embryos are given away?
>
> Junior IVF clinician 1: But they ... most of the patients do not care about what research we are doing. They just focus on ... if they can get successfully pregnant (laughs). [...] You know, most of them just don't have any questions about it. They just go over it. They agree or disagree and then talk about other things. They don't focus on this ... this is not their focus.

Younger clinical staff members, in particular, appear to carry out informed consent procedures in careless and sometimes highly irresponsible ways. Occasionally, the conversations that accompanied the IC process appear to be characterized by the

calculated handling of silence, that is, the facilitation of "choice" through strategic games of information concealment and disclosure. In some cases, the conversations with patients also included elements of overt deception and the making of untenable promises:

> I: How many percent of patients want to provide their embryos after you have talked to them?
>
> Junior IVF clinician 2: Mm, maybe 75%.
>
> I: Oh, that is a lot!
>
> Junior IVF clinician 3: Yes but that is because we encourage (*guli*) them, we persuade (*shuofu*) them.
>
> I: How do you do this?
>
> Junior IVF clinician 3 (laughs and points to Junior IVF clinician 2): She is good at this (laughs again). She is doing this very well, to persuade patients.
>
> Junior IVF clinician 2: I tell them that it is useful for scientists and useful for mankind, in the future, probably ... And, OK, I will make sure that the donated embryos will not be given to other people, so that they know they will not have another baby.
>
> I: And what else do you tell. How do you try to persuade a patient so that she really ...
>
> Junior IVF clinician 2: If patients come to our hospital their purpose is to have a baby, they do not care too much about the remaining embryos. [...] I tell them that the stem cells [derived from their donated embryo] can maybe be used for their children, in case they have a disease that can be cured in the future.
>
> Junior IVF clinician 3: If their child has leukaemia, for example, maybe our research would help to cure these diseases. Maybe the patients, if they hear this, they think it is better for their child [if they donate], so many times they will agree.

Similar tactics of leading patients to believe that stem cells derived from their donated embryos might directly benefit the future health of the donors or the donor's child could also be observed in another clinic. As a clinician in a senior position told me, occasionally he would tell patients the following:

> Senior IVF clinician 7: If in the coming days, there will be the necessity that you use the stem cell line [established from your embryo] for medical purposes, we will check whether your embryos have become a cell line, what and where the cell line is today, and whether it is possible to use this line for you. If in the future there is a technique, you are the first to use this technique. You have the privilege to use the stem cells.

I do not want to preclude that such promises are—at least partly—based on good intentions or at least on a genuinely optimistic attitude toward the medical potential of stem cell research. However, it is obvious that these conversations contain elements of deception and manipulation. In addition to this, from a legal perspective, such claims remain unsupported. In the consent forms that patients sign, it is unmistakably specified that with the act of donation, the donor gives up all future rights on the embryo, including any claim to get access to future therapies or economic profits derived from the research for which donated embryos have been used.

14.5 How is the Use of hESC Lines Regulated? China in Comparison with the UK

hESC cell lines created in China are distributed in relatively complex and difficult to oversee networks within, but also across, national borders. To understand how the distribution of hESC can be used for the extraction of specific forms of value (and how these forms of values could benefit embryo donors and citizens), it is necessary to know more about the regulatory conditions under which these exchanges occur. I have decided, in this regard, to briefly compare the regulatory situation in China with the situation in the UK. The reason for this is that the UK is, to my knowledge, the only country in the world in which distribution of hESC lines occurs under the centralized and legally binding control of a centralized institution: the UK Stem Cell Bank (UK-SCB). In contrast to the UK, where the distribution of hESC lines occurs entirely under the supervision and rules of the UK-SCB, the movement of hESC lines in China occurs in a more open and, in a regulatory sense, also a less stringent system. However, let us first look at the situation in the UK. In the UK, the transfer of hESC lines is permitted only after the completion of a wide range of meticulously prescribed check-up procedures, which range from informed consent protocols to standardized assessment procedures for cell characterization and quality control. The UK-SCB steering committee plays a crucial role here, as it checks the license, qualifications, reputation, research objectives, and capacities of applicant centers. In case of requests from centers abroad, the committee still evaluates the legality of the proposed research project in the acquiring country (Stephens et al. 2008). A further responsibility of the committee is to negotiate with applicant centers the precise conditions and terms of use of the attained cell materials. Agreed conditions must fully comply with the UK-SCB's code of practice. Transgression is punishable in law (Warrell 2009).

This situation differs significantly from China, where individual research institutes manage the distribution of hESC samples, and regional government branches carry out the necessary controls. Furthermore, a huge difference exists in China regarding the transfer of hESC materials within and across national borders. While transfers of hESC samples within China seem to occur on the basis of the institutes' internal approval procedures, a considerably more complex regulatory picture emerges in the case of transfers of hESC samples abroad. Here, two basic requirements must be met. The first is to obtain approval from the Chinese Inspection and Quarantine Bureau, which handles an online registration system and which has specified the conditions that apply to the transfer of human tissue in the "Work Norms for the Health Quarantine Examination and Approval of the Entry/Exit of Special (Biological) Items," a nationally binding memorandum issued in 2006. No distinct set of specifications, however, exists for the transfer of hESC samples in this document, which fall under the same category as blood, bone marrow, cord blood, and other tissue commonly used for medical purposes. Documentation requirements for this category include a range of standard operating procedures for the identification of cell identity, quality, and the presence of microbial contaminants

and biohazards. Further requirements include a description of research purposes and potential risks.

The second requirement is the setting up of a Material Transfer Agreement (MTA), a document that has to be signed by the Chinese Human Genetic Resources Control Office (HGCO). The MTA specifies the conditions and terms of use of exchanged tissue as negotiated and agreed upon between the exchange partners. Besides issues related to intellectual property and benefit sharing, the document must include a technical description of the research and a risk assessment and safety evaluation form. The HGCO checks also the license and qualifications of the tissue recipient abroad. Once the MTA has been authorized, a local branch of the Inspection and Quarantine Bureau issues a final approval document (Warrell 2009).

A key difference from the UK is that neither the HGCO nor the Inspection and Quarantine Bureau carries out controls of issues relevant to the ethical oversight of the transfer of hESC samples, such as the documentation of appropriate informed consent. Furthermore, while research purposes and related risks, together with the license, reputation, and capacities of tissue recipients, are assessed in case of international transfers, in domestic transfers such controls are performed by individual research institutes. As I will show now, these differences have implications with regard to the benefits that can be achieved by researchers, embryo donors, and the wider citizenry.

14.6 Benefits for the National Community?

A widely expressed claim that IVF clinicians communicated to potential embryo donors was that the donation and use of embryos for research would contribute to the improvement of the future health of fellow citizens. As one of the IVF clinicians with whom I spoke put it: "We tell our patients that *the whole society* may benefit from the donation of their embryos in the future" (emphasis mine). Donation is portrayed here as an act of altruism and solidarity. Present-day citizens help, through their donation, the well-being of future citizens, a selfless expression of help that might also benefit oneself and one's family. While this may be true for more wealthy citizens of high-income countries with comprehensive health care systems, these representations provide donors with a biased and rather one-dimensional picture of the benefits that can be extracted by the donation and usage of embryos. Three points deserve attention in this regard.

First, many of the hESC cell lines that have been created over the past years have been distributed to research laboratories all over the world. However, the dispersion of places in which research is carried out implies also the spatial dispersion of therapeutic applications. As I have shown elsewhere (Rosemann 2011), the distribution of stem cell lines across borders is likely to result in the extraction of benefits that are shared beyond the relations of national citizenship, events that considerably contradict with the perceptions of most embryo donors in China, who are left in the belief that research findings contribute, in the first place, to the national health

community. A justified concern in this regard is that access to these developing therapeutic possibilities will be highly selective, across national borders as well as within. Unlike blood, for example, whose donation benefits people regardless of their socioeconomic status, the donation of embryos for the labor-, technology- and capital-intensive stem cell research is likely to benefit exclusively the more wealthy segments of national populations. In low-income countries such as China, that means that larger parts of the population might be excluded from access to these therapies, including the majority of people who had donated their embryos for research.

Second, the one-sided focus on the communication of the health value of stem cell research neglects all other forms of value that are hoped to be extracted on the basis of hESC research, among which the accrual of profits by pharmaceutical companies and the biotech industry, the realization of political ambitions as well as financial gains, and increases in status for individual scientists and research centers.

Third, the communication of the future value of hESC research in terms of "benefits for the national citizenry" neglects to account for the concrete forms of value and benefit that the derivation, use, distribution, and circulation of hESC lines has for scientific user communities in the present. As I have shown in another publication (Rosemann 2011), the use and exchange of hESC lines between different research labs is producing various forms of value for researchers and research centers. These are not elusive forms of "future value" but tangible forms of "present-day value" that range from career benefits to the attainment of workforce, to augmented numbers of publications, to the initiation of national and international research collaborations, and to the initiation of sustained chains of exchange with other researchers and corporations. While these processes in themselves are in general positive and they are as they should be, it is nonetheless striking that these benefits remain completely unspecified in the everyday practice of embryo donation.

14.7 Conclusions

In this chapter I provided insights into the communication processes through which the donation of embryos is facilitated in IVF clinics in China. A varied picture emerged here that offered insights into practices that unfolded between the poles of a strong commitment to professional care and high responsibility awareness, on the one hand, and forms of deception and untenable promises, on the other hand. On average, differences in attitudes and practices could be noted between clinicians and researchers in lower and higher professional positions. These gaps between promoted principles of good practice at the top level and actual practices at the level of the bedside indicate a lack of adequate ethical training of clinical staff or researchers. The chapter clarified, furthermore, that there exists a fundamental gap between the ways in which the value of the donated embryo is communicated to donors and

the forms of value that are extracted by hESC researchers and corporations. In the IVF clinics I visited, the donation of embryos for hESC research was framed primarily as an act of solidarity, which exemplified a selfless expression of support from citizen to citizen. However, in the light of the complexities and stumbling blocks of present-day systems of human tissue circulation and the concrete forms of benefit and profit that the derivation and possession of stem cell lines creates for user communities in the present, such claims are misleading. Cross-culturally informed types of bioethics recognize that there are variations in the ways in which social phenomena and processes are categorized and problematized. However, from my understanding, some of the practices I encountered did clearly transgress the (admittedly difficult to define) borderlands of mutual respect and the positive recognition of difference. The observed ways in which patients were misled by some clinicians are intolerable according to Chinese guidelines for embryo donation and according to international standards, as provided, for instance, by the International Society for Stem Cell Research.

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