Published in final edited form as:

Fertil Steril. 2012 February ; 97(2): 427–433. doi:10.1016/j.fertnstert.2011.11.035.

Informing egg donors of the potential for embryonic research: A survey of consent forms from US IVF clinics

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Abstract

Objective—To understand whether and to what extent US *in vitro* fertilization (IVF) clinics inform egg donors that resultant embryos initially intended to be implanted for reproductive purposes may in fact be used for research instead.

Design—470 US IVF were asked to respond to a questionnaire and provide a copy of the egg donor consent form(s) used at the clinic.

Setting—470 US IVF clinics listed in a Centers for Disease Control and Prevention database; only forms from clinics that both accepted donor eggs and provided excess embryos for research were analyzed for content.

Main Outcome Measures—Responses to the questionnaire, demographic data from a Centers for Disease Control and Prevention database and the content of egg donor consent forms.

Results—Of 222 US IVF clinics who responded to our query, 100 clinics both accepted donor eggs and provided some excess embryos for research. We received 66 consent forms from these 100 clinics, which showed that although most egg donor consent forms inform donors that they will not have control over embryos resulting from their eggs, 30% inform them that some embryos may be used for research, and even fewer mention stem cell research.

Conclusion—Egg donors in the US, including some who may have a moral objection to research and stem cell research, are not being informed that embryos created with their donated eggs may in fact be used for these purposes. This can be corrected with the inclusion of succinct, non-technical language in egg donor consent forms.

Background

Human embryonic stem cell research has been a lightning rod of controversy in the United States since the first embryonic stem cell lines were derived in 1998. (1) Most of the controversy evolves from the provenance of the lines; the derivation of cells to develop an

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embryonic stem cell line usually results in destruction of the embryo, which some view as unethical. The Dickey-Wicker amendment, a part of the National Institutes of Health appropriations bill approved annually since FY1996, (2) prohibits the use of federal funds for the creation or destruction of embryos for research purposes. Current DHHS guidelines, however, allow federal funding for research with embryonic stem cells derived from spare embryos created for reproductive purposes through *in vitro* fertilization (IVF), but that were no longer needed for reproductive purposes. Among other requirements, the guidelines require that at the time of donation, individuals seeking IVF treatment give their informed consent to donate spare embryos for research and provide details of what the consent process must include for individuals donating an embryo. (3)

While the majority of embryos created for reproductive purposes in IVF clinics utilize eggs derived from the same woman who is undergoing IVF treatment, in about 12% of cases a donated egg from a separate donor is utilized for those undergoing IVF treatment. (4) Donors are generally provided with a consent form that details the process of donation and the procedures and burdens they will undergo. As is true in IVF treatment with non-donor eggs, donated eggs are fertilized to create embryos suitable for implantation, but some embryos may not end up being implanted. Some 'spare' embryos are frozen for later possible implantation, and others are ultimately discarded or donated for research, including research involving the derivation of stem cells. The NIH stem cell guidelines require consent from individual(s) undergoing IVF treatment, but do not specify requirements for informed consent from the egg donor. In response to public comments on these guidelines, the NIH notes that a) individuals undergoing IVF treatment, not egg donors, are responsible for the creation and disposition of embryos, and b) research risks to gamete donors are privacy-related, and therefore covered by the Common Rule (45 CFR 46). (3)

Egg donation is itself a burdensome and risky procedure. Besides the physical risks of donation, there may be other risks to egg donors. Recent surveys have found that approximately a third of Americans have serious moral objections to stem cell research; (5, 6) While no study has estimated the percent of egg donors who have such objections, these general surveys indicate that at least some are likely to. A woman with moral objections to embryonic stem cell research might refuse to donate if she knew it was possible her eggs could ultimately be used for such research. Therefore, in addition to the physical risks of egg donation and possible privacy risks from research, egg donors may also be at risk of participating in a process about which they are not aware but would oppose if they were. This opposition might originate in concerns about embryo destruction, or in more general concerns about research. Although individuals responsible for the creation of embryos may justifiably have control over the disposition of those embryos, including information about potential research use in egg donors' consent forms may be an appropriate mechanism to ensure that only those who are comfortable with embryos potentially being used for research would donate their eggs. This suggestion does not rely on any particular position on the morality of embryonic research, but rather on the recognition that some egg donors may object to the morality of embryo research; this objection, whether justified or not, makes informing donors about the potential for research particularly important.

Similar reasoning has led to recommendations that IVF clinics inform oocyte donors that resultant embryos might be used for research. (7, 8) While the American Society of Reproductive Medicine's (ASRM) ethics committee is somewhat ambiguous on this point, (9) guidelines on stem cell research from the National Academy of Sciences (NAS) (10) as well as the International Society for Stem Cell Research (ISSCR) (11, 12) recommend that gamete donors be informed about potential embryonic research. However, practice does not always conform to such nonbinding guidelines. Streiffer found, for example, that consent

forms for couples whose embryos generated stem cell lines eligible for federal funding prior to 2009 failed to comply with NAS recommendations on a number of dimensions. (13)

To date there has not been a comprehensive study of egg donor consent documents, in particular with respect to the extent of information on research. Without such data, it is difficult to determine whether standard practice is in need of reform. We sought to discover whether and to what extent egg donors at IVF clinics in the United States are informed that embryos created with their eggs may ultimately be donated for research, including stem cell research.

Methods

This is a cross sectional, descriptive study of whether and how egg donor consent documents at U.S. IVF clinics describe research in general, and stem cell research in particular. The sample was derived from a list provided by the U.S. Centers for Disease Control and Prevention used in their annual survey of IVF clinics in the US. (4) An initial phone contact was made in spring 2010 to each of the 470 clinics in the database. A letter followed in June 2010 describing the purpose of the study, asking a few questions, and requesting a copy of the informed consent documents used by the clinic for oocyte donors. Reminder phone calls were made approximately 3 weeks later.

This study was determined to be exempt from IRB review by the NIH Office of Human Subjects Research. The advance letter informed potential respondents of the study purpose and that completion was voluntary and responses anonymous.

Clinics were eliminated if they were untraceable (45) or no longer offered IVF (10). A total of 102 explicitly declined participation. Of the remaining 313 IVF clinics, 222 responded. A total of 210 (of the 222) clinics said they accept donor eggs, and 100 of those provide at least some excess embryos for research. Clinics (n=100) were considered “eligible” for analysis if they both accepted donor eggs and provided excess embryos for research. We received 66 consent forms from the 100 eligible clinics. In addition, we received 44 forms from clinics that were ineligible for and not included in our analysis because they did not provide excess embryos for research. One clinic initially responded that it did not accept donor eggs; however, that clinic sent a consent form clearly intended for egg donors, indicating that their initial answer was an oversight. We therefore classified the clinic as eligible and included the consent form in our sample. This was the only discrepancy we found between survey responses and consent form analysis.

Consent forms were reviewed by two individuals (neither of whom are subordinate to the authors) at the Center for Survey Research at the University of Massachusetts to determine whether or not they included nine pieces of information as shown in Box 1. The nine elements, several adapted from the 2009 NIH stem cell guideline requirements for embryo donors, (3) were chosen as possibly relevant to a woman's decision to donate her eggs. Each item was coded as to whether it was present in the consent form. Coders further evaluated whether or not the language about control and excess embryos were explained.

Discrepancies were resolved by the two raters in consultation with the authors. The total length (in pages) of each form was also noted. In addition, each clinic's general geographic region (Northeast, Midwest, West, and South), membership in the Society of Assisted Reproductive Technologies (SART), and accreditation, as well as the total number of annual egg transfers of embryos derived both from donor eggs and from non- donor eggs (as documented in the CDC's database) were noted.

Data were described using frequency distributions and simple descriptive statistics. Categorical variables were compared using Fisher's exact tests and continuous ones using Wilcoxon rank-sum tests. Data were analyzed using SAS v9.2 (SAS Institute, Inc, Carey, NC), and all p-values less than 0.05 were considered statistically significant.

Results

Clinic demographics

Demographic characteristics of the IVF clinics for each response category are shown in Table 1. While clinics in the Midwest and West were slightly more likely to both accept donor eggs and to donate embryos for research than those in the Northeast or South, these differences were not statistically significant ($p=0.14$). Indeed, no statistically significant differences in geographic location, accreditation, or SART membership were found between responding vs. non-responding clinics, eligible vs. ineligible responders, or eligible clinics that sent consent forms vs. those that did not.

There were, however, several statistically significant differences related to the number of assisted reproductive technology cycles performed in 2007 (the latest year from which CDC data were available at the time of analysis). Clinics that responded to our inquiries had performed a significantly higher number of cycles using non-donor eggs compared with non responders ($p = 0.0053$). Among those clinics that did respond, eligible clinics performed significantly higher numbers of both non-donor ($p < 0.0001$) and donor ($p < .0001$) cycles as compared with ineligible clinics. Among the eligible clinics, however, there were no such differences observed between those that sent consent forms and those that did not.

Questionnaire results

The vast majority of eligible IVF clinics (95%) confirmed that they had a consent form for egg donors; although 3 of the eligible clinics did not answer this item, 2 sent consent forms that were included in the analysis. Surprisingly, 2 clinics (2%) responded that they had no such forms (Table 2). Among the 100 eligible clinics who donated some excess embryos for research, 54 (54%) said at least some excess embryos are used for stem cell research. Clinics in the Northeast, Midwest and West were slightly more likely than clinics in the South to donate some embryos for stem cell research ($p = 0.0246$). See Table 2 for further information on the extent to which eligible clinics allowed recipients to know egg donors' identities, allowed directed donations and retained identifiable information on donors.

Analysis of Consent forms

Of 100 eligible clinics, 65 sent a total of 66 consent forms for analysis. Although several clinics submitted separate forms for anonymous and directed donors, forms for anonymous and directed donation from one clinic had significantly different content; therefore both were included in the analysis as distinct, making the total analyzable sample of consent forms 66. See Table 3. Consent forms averaged 4.9 pages in length (median 4.0, range 1-26).

Almost all forms (97%) included language regarding control over donated eggs, the resultant embryos, and/or resultant children. Among those, most ($n=60$, or 94%) stated that the donor would have no control whatsoever. A typical statement read as follows: "Donors agree to waive, relinquish, and/or give up any and all rights to egg, embryos and any child(ren) resulting from the eggs donated." In contrast, 4 forms (6%) described some measure of control for the donor, explaining options and allowing egg donors to indicate their choices related to the disposition of embryos created with their eggs. In two cases, donors appeared to have the option to decline or to explicitly allow excess embryos to be used for research.

Forms mentioned control over eggs and/or embryos (92%) slightly more than control over resultant children (85%). Less than half (23 of 60 or 38%) of forms mentioning egg/embryo control explained what it meant to lack (or have) control over eggs/embryos. One example of language explaining control said: "Any unused eggs will be the sole property of the recipient(s). My recipient(s) will have sole jurisdiction over the embryos. She may decide to donate the embryos to another person(s) for research." Such language goes beyond merely mentioning waiver of rights, delineating more precisely what privileges the donor is giving up.

Most IVF clinics produce excess embryos--that is, embryos that do not end up being implanted for reproduction. The majority of forms (70%) stated that some embryos might be excess. Just under half of those (21/46 or 46%) explained what it meant for an embryo to be in excess, for example explaining that, for embryos not implanted, a recipient might choose to freeze, discard, donate to another couple, or donate to research. In addition, 29 of 66 forms (44%) indicated that some embryos might be discarded or destroyed.

Just 20 of 66 egg donor consent forms (30%) informed donors that embryos could ultimately be used for research. Also, while 38 clinics stated that some embryos are donated for stem cell research, only 3 (8% of the clinics that allow embryos to be donated for stem cell research) inform egg donors of this possibility. Few consent forms included additional details about the possibility of research.

Consent forms that mentioned research were more likely to explain control over eggs and embryos ($p = 0.0015$), mention that some embryos would be in excess ($p < 0.0001$) and might be destroyed ($p < 0.0001$). No other statistically significant associations were found.

Discussion

Our data show that a significant majority of egg donors in the US are not informed, and thus may not be aware, that their donated eggs will be used to create embryos that could ultimately be used in research, including stem cell research. In this analysis of egg donor consent forms from IVF clinics in the US that provide excess embryos for research, only a minority of forms (30%) followed NAS and ISSCR recommendations and informed egg donors about the possibility of research. Also, while more forms mentioned embryonic destruction, a significant source of probable objections to research, a majority (56%) did not. Consent forms that did mention research had more detailed information overall about who had control over the created embryo and about possible embryo outcomes, indicating that those clinics that mention research in the consent form often gave donors more comprehensive information about what might happen to embryos resulting from donated eggs than clinics that did not mention research.

We, like others, (7, 8) believe that IVF clinics should inform egg donors that some embryos derived from their eggs will not be implanted, could be discarded, and might be used for research, including stem cell research. Stem cell research is sufficiently controversial that it could dissuade certain individuals from donating their eggs. If consequently fewer women donated eggs, it could have a negative impact on couples seeking IVF treatment. However, the alternative is to allow egg donations from women with moral objections to research who, if fully informed of the possible outcomes for resulting embryos, would choose not to donate. Given the burdens associated with egg donation and the strong views about stem cell research held by some members of the public, IVF clinics should aim to ensure that egg donors are fully informed about the possibility of excess embryos, and that some of those embryos may ultimately be discarded or donated for research, including stem cell research.

Although the vast majority of consent forms indicate that the egg donor will not have control over the disposition of resultant embryos or children created using their eggs, it may not be sufficient for donors to simply agree to give up control without more information about what that entails. At the very least, clinics should try to better inform donors. Explaining that giving up control over embryos includes giving up the right to choose whether to donate embryos for research could help to reduce the risk that egg donors will unwittingly contribute to research to which they seriously object.

Notably, a small number of forms (4) did afford donors some control and allow donors to indicate their choices related to disposition of embryos created with their eggs. We are not advocating that egg donors always be given control over the disposition of embryos and recognize that clinics may have good reasons to not give such options. Giving egg donors control over embryo disposition might be too restrictive on those seeking IVF. However, providing some choices over embryo disposition may be feasible in certain cases and could provide advantages over simply informing donors of the possibility of research. While we do not recommend such control be given generally, its advantages should be considered and it should not necessarily be ruled out. A woman who might choose not to donate eggs if provided information about possible research on a resulting embryo might still choose to donate if she was given some control over such use. This, in turn, could soften any potential impact on the number of donors. In addition, individuals would then have the option to donate eggs without compromising any moral convictions involving research or the destruction of embryos that they may hold.

It is noteworthy that almost no forms included information on research beyond the basic NAS and ISSCR recommendations. We recognize that egg donors need not be given the full gamut of information required for those donating embryos for research, including information on medical benefits and commercial potential. The kind of information relevant and useful for an egg donor is different from what should be provided for a couple donating an embryo for research. Egg donors are, for example, less likely to expect personal medical or financial benefit from research. Briefer information that alerts donors to the possibility of research should be sufficient to ensure those that have serious objections to research do not end up unwittingly contributing to it. Because stem cell research is particularly controversial mentioning it explicitly seems important. In addition, clinics should provide more explanation regarding available options for excess embryos.

Providing this additional information need not take up much space to be effective. The following phrasing concerning embryos created using donor eggs conveys the information in a succinct and non-technical way:

Some embryos might not be implanted, and recipients might instead opt to discard them or donate them for research, including stem cell research. In the course of such research, the embryos might be destroyed.

Clinics that specifically support stem cell research could also consider adding a sentence or two explaining what stem cell research involves; some donors, for instance, might also be uncomfortable with the fact that stem cell lines will exist in perpetuity. We are not advocating that IRBs enforce such language in egg donor consent forms; however, believe that clinics have a responsibility to inform donors about potential research uses for resultant embryos.

One might wonder whether similar reasoning would justify the inclusion of additional information about the people who might receive the donated egg. For instance, perhaps some women would not donate if they were informed that their egg might be used by a gay couple seeking IVF treatment. Does this mean that anonymous egg donors should be

informed of all the different types of individuals who might potentially use their donated egg? We think not. Anonymous donors are already explicitly informed that their eggs will be used for reproductive purposes by unknown individuals. Without language concerning other possible non-reproductive uses of a resultant embryo, however, donors might erroneously think that all embryos made with their eggs are used only for reproductive purposes. . It is this lack of knowledge that is problematic.

One might also object that language concerning embryonic destruction but not research is necessary because much of the opposition centers on objections to the destruction of embryos. Providing information about embryo destruction is indeed important. However, it is plausible that some may have objections to embryonic research over and above the fact that embryos are destroyed in the process. There could be concerns over privacy and donor identification, the fact that stem cell lines may exist in perpetuity, or the idea that the embryos are being used for purposes other than reproductive therapy. Moreover, whether or not donors' views about the morality of research and destruction are cogent or inconsistent, we should be mindful of them in the consent process. Informing egg donors about research is a relatively simple way to respect those views and ensure that donors do not end up undertaking a burdensome procedure they would have avoided had they been aware of the potential for research.

More information concerning donor attitudes toward research and destruction, a topic that came up incidentally in one study would be informative (8) We have argued that the potential for serious objections to research is sufficient to warrant a change in consent for egg donors, more systematic data on whether and to what extent donors have worries about research above and beyond the potential for embryonic destruction would inform those changes.

Limitations

About half of all the IVF clinics in the US (as documented by the CDC) responded and two-thirds of eligible responders sent consent forms, resulting in some risk of selection bias in this study. This level of response engenders care in the generalizability of results. Clinics with less rigorous informed consent procedures may have been less inclined to participate in a study on donor consent and our results might overestimate the rate at which clinics provide information related to embryo control, outcomes and research, though, the opposite is also possible. The 220 responding clinics did perform more non-donor cycles than non-responders, and thus were most likely larger clinics that handle more patients. Such clinics may have larger staffs that could more easily handle requests such as ours. However, clinics that performed more cycles were not more likely to send us consent forms, and the number of cycles did not correlate with likelihood to provide information on consent forms, making clinic size an unlikely source of bias in our results.

Conclusion

Consent forms for egg donors in U.S. IVF clinics more often than not fail to inform donors about the possible research use and/or destruction of excess embryos created from their eggs. Since possible research use of embryos, especially for stem cell research, may be material information affecting some women's decision about donation, egg donors should be so informed. We have suggested some research language that could be inserted into egg donor consent forms; we hope that clinics and professional societies will see the ethical merits of including such information and revise practice accordingly.

Acknowledgments

The authors are grateful to the IVF clinics who sent consent forms and answered our questions, to Brian Clarridge, Swaati Eklund and others at the University of Massachusetts Center for Survey Research, to Andrea Kalfoglou and Annie Lyerly who offered useful advice about this study, and to Alan Wertheimer, Seema Shah, Benjamin Berkman and Sara Hull for their helpful comments. All authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Funding and support for design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript was provided by the National Institutes of Health Clinical Center.

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Table 1
Clinic Demographics

Characteristic	Total CDC cohort (n=470)	Clinics that responded to questionnaire (n=222)	Clinics eligible * for consent analysis (n=100)	Eligible clinics who sent consent forms (n=66)
Region (%) **				
Northeast	21	22	22	23
Midwest	22	23	26	27
South	32	31	24	21
West	25	24	29	29
SART member (%)	88	88	93	90
Accredited (%)	91	90	95	95
Cycles using nondonor eggs †				
Mean ± SD	290 ±413	319 ±404	449±505	429 ±440
Median (IQR)	153 (81-33)	183 (103-359)	283 (146-522)	305 (166-585)
Cycles using donor eggs				
Mean ±SD	38 ±56	38±48	60 ±61	58 ±62
Median (IQR)	18 (7-48)	20 (9-47)	37 (17-89)	37 (17-86)

* both accept donor eggs and donate embryos for research

** 3 clinics located in Puerto Rico were not included in the distribution by region

† data available for 412 of 470 clinics, 209 of 222, and 98 of 100

SD = standard deviation

IQR = inter-quartile range (25th percentile-75th percentile)

Table 2

Characteristics of eligible clinics

Questions about eligible clinics	Response in %-eligible clinics (n=100)			Response in %-eligible clinics that sent consent forms (n=66)*		
	Yes	No	No response	Yes	No	No response
Are some of your excess embryos used for <i>stem cell</i> research?	54	43	4	58	38	4
Do you have a consent from that you use with egg donors?	95	2	3	97	0	3
Does your clinic allow the recipients of a donated egg to know the identity of the egg donor?	12	34	51	9	33	53
Does your clinic allow egg donors to direct their donation to a specific couple?	57	16	26	53	17	27
Does your clinic retain any identifiable information which could link an embryo back to an egg donor?	82	10	6	86	5	6

* 1 eligible clinic submitted 2 consent forms.

Table 3

Consent form analysis (n = 66) of eligible clinics.

Control	Yes	No
Is there language about who has control over what happens to the eggs, embryo, and/or child?	64 (97%)	2 (3%)
If so:		
Does the language allow any control at all?	4 (6%)	60 (94%)
Does the control language mention parental control?	56 (88%)	8 (12%)
Does the control language mention eggs and/or embryos?	60 (95%)	3 (5%)
If so:		
Does the form explain what it means to lack (or have) control over eggs/embryos?	23 (38%)	37 (62%)
Outcomes		
Does the form indicate that some embryos created using donated eggs will be excess?	46 (70%)	20 (30%)
If so:		
* Does the form <i>further explain</i> that embryos may be excess?	21 (46%)	25 (54%)
Does the form indicate that some embryos may be discarded or destroyed?	29 (44%)	37 (56%)
Research		
Does the form indicate:		
that excess embryos created using donated eggs could ultimately be used for research?	20 (30%)	45 (68%)
** that excess embryos could be used to derive stem cells for research?	3 (8%)	35 (92%)
that embryos used in research might no longer be implantable because, for example, they would be destroyed or irretrievably altered for research?	1 (2%)	65 (98%)
that the research is not intended to provide medical benefit to either the egg donor or embryo donor?	2 (3%)	64 (97%)
that neither the egg donor nor the embryo donor can direct or restrict who might receive any medical benefits from the research?	0 (0%)	66 (100%)
that the results of such <i>research</i> may have commercial potential, and neither the egg nor embryo donor would receive any financial benefits	1 (2%)	65 (98%)

* Restricted to the 46 consent forms that indicated that some embryos will be excess.

** Restricted to eligible clinics that indicated they do donate some embryos for stem cell research (n=38).