

Informed consent and the use of gametes and embryos for research

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The ethical acceptability of research involving human gametes and embryos has been affirmed by national commissions and committees and published in their respective reports (1). In view of the public concern about human embryo research, the ASRM advises that the investigator bear the burden of demonstrating the worthiness of studies involving human embryos and that embryos be studied only when there is no adequate alternative, the study is likely to yield important clinical data, and the number of embryos is kept to a minimum.

A critical component of ethical research is the clinician's obligation to obtain Institutional Review Board (IRB) approval and to secure informed consent from the donors of oocytes, spermatozoa, and embryos.

In general, patients must give consent for any research use of their cells or tissues. In the field of assisted reproduction, the following cells and tissues might be studied: oocytes, spermatozoa, normal but spare fresh or frozen embryos not needed by couples in IVF programs, nonviable or abnormal embryos, abnormally fertilized eggs that will not be transferred to the uterus, and eggs and sperm used to generate embryos intended for research but not transfer. Although informed consent should be obtained before any of these cells or tissues are studied, the most sensitive issues arise for research in which viable embryos are studied or generated for study and then discarded. Informed consent protects donors and investigators and it encourages clarity in the clinic's prospective research plans. Precise statements about intended benefits and methods are also desirable to help address misconceptions patients and members of the public may have about embryo research.

Prospective donors in assisted reproductive programs must be assured that nonparticipation will not adversely affect their status in the program. They should have access to material that informs them of the goals and benefits of the research and, if they request, articles that raise and address ethical concerns about embryo research. They should be apprised if the cells or tissues they donate will yield an expected commercial value for the investigators. It is imperative that couples not feel pressured to donate. Gamete and embryo donation for research must not be induced by financial payment, although donors may be compensated for expenses associated with donation.

Clinicians should be aware that couples may change their minds and decide not to donate their gametes or embryos for study. Couples should be informed that it is possible to change their minds without prejudice at any time until the experiment actually begins, and clinicians should inform couples about the mechanisms to be used if the prospective donors decide not to participate. Investigators should make clear that once embryos are donated for research and not for transfer, and experimental manipulations begin, the embryos cannot be transferred for possible pregnancy.

To secure informed consent, clinicians must provide enough information for prospective donors (those part of an assisted reproductive program or anonymous gamete donors) to make an informed choice about whether to participate. This includes informing potential donors of the purpose, nature, and risks and benefits of the research. The research purpose is important because prospective donors may be willing to donate for some purposes, such as studies designed to improve success rates in assisted reproduction, but not for others, such

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as inquiries into cancer or contraceptive research. Other donors will have no such preferences. The nature of the research is important because prospective donors may be willing to donate for some types of studies, such as those involving passive observation of embryos, but not for others, such as those involving active manipulation of embryos. Whether the embryos to be studied are normal and viable or abnormal and nonviable may also be important for the donors. Anonymous oocyte and sperm donors must consent to have their gametes used to generate embryos for research purposes. Investigators should obtain consent to discard or donate embryos or gametes that cannot be used in ways stipulated by the donor. They should obtain reapproval by the IRB if significant changes are made in the purpose or nature of the research, and they should generate a new consent form for the donors after a discussion of the changes.

Regarding the benefits and risks, couples who donate spare embryos for research should be informed that the benefit will take the form of advanced knowledge and that they will not directly benefit from the study. Donors should also be aware that any discoveries in their gametes or embryos such as the presence of a genetic mutation will not be

conveyed to them. They should be advised that one risk is that they may later regret not having saved the embryos for their infertility treatment or for donation to other couples.

Consent forms should receive prior approval from the IRB or equivalent oversight committee. Consent to study gametes should be sought before the collection of a semen sample or oocyte recovery, when potential donors have time to consider consent forms and other material. Physicians should secure consent with a witness present and then place the consent form in a confidential file.

In summary, a carefully specified procedure for obtaining informed consent is vital for the ethical implementation of studies involving human gametes and embryos. In order to preserve the interests of the infertile population, all research activities must be performed with strict attention to ethical standards. Informed consent, along with active IRB involvement and confidentiality, remain the best vehicles for assuring this protection.

Reference

1. National Institutes of Health. Report of the Human Embryo Research Panel: Final Draft, September 27, 1994. Bethesda, MD: National Institutes of Health, 1994.