Is Embryo Adoption a Form of Surrogacy?

Ryan C. Mayer

Abstract. The author applies the definitions of surrogacy offered by *Donum vitae* to the question of embryo adoption and shows that embryo adoption does not in fact constitute an act of surrogacy. The author shows that neither *Donum vitae* nor *Dignitas personae* condemns heterologous embryo transfer or embryo adoption per se but only when these acts also involve illicit forms of artificial fertilization or surrogacy. The author suggests that the apparent reason for a lack of endorsement of embryo adoption by *Donum vitae* and *Dignitas personae* is pastoral caution, concern for scandal, and the connection between embryo adoption and IVF; it is not because embryo adoption is intrinsically illicit. *National Catholic Bioethics Quarterly* 11.2 (Summer 2011): 249–256.

Nowhere is it more evident than in the field of reproductive technology that, as the colloquialism suggests, man's reach exceeds his grasp.[1] In just forty years, what was only the content of science fiction and *Brave New World* has become not only possible but mainstream. In vitro fertilization and embryo transfer are becoming more and more commonplace not only in practice but even in common verbiage. One Web site "dedicated to babies conceived via assisted reproductive technologies"

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[1] The original quote from the poem *Andrea Del Sarto* by Robert Browning reads, "Ah, but a man's reach *should* exceed his grasp" (emphasis added). Such a quote could serve as a fitting motto for a utilitarian ethic.

even sells clothing for newborns emblazoned with slogans such as "IVF Baby" and "My parents went through IVF and now all they can afford is this lousy t-shirt."[2] Our technological reach seems to have exceeded our moral grasp.

As the ever insightful and prophetic G. K. Chesterton once remarked, "We are learning to do a great many clever things … the next great task will be to learn not to do them."[3] But while we learn not to do many clever things, an immediate and serious moral question has been raised by our technological ability to make human life outside of the conjugal embrace, namely, "What can licitly be done with those human embryos that have been made and remain as a result of IVF?" These embryos, often labeled "leftover" or "surplus," are left frozen in limbo in what geneticist Jérôme Lejeune famously referred to as the "concentration can."[4] What can be done for these tiny human beings who, in the first moments of their lives, are already exposed to such an absurd state as the deep freeze of liquid nitrogen?[5]

Technically speaking, the possibilities are as follows: the embryos can be (1) discarded, (2) used in research, (3) left frozen—a fate *Donum vitae* calls "absurd," or (4) transferred into a woman's womb and allowed to gestate to term. When the woman is both the embryo's genetic mother and the wife of the genetic father this is called homologous embryo transfer. When the embryo is not the woman's genetic child, this is known as heterologous embryo transfer (HET).

Catholic moral theologians are united in their condemnation of experimental exploitation and the willful destruction of these embryos (possibilities 1 and 2). *Donum vitae* also expressly condemns both practices asserting, "Just as the Church condemns induced abortion, so she also forbids acts against the life of these [embryonic] human beings. … Methods of observation or experimentation which damage or impose grave and disproportionate risks upon embryos obtained *in vitro* are morally illicit."[6] This was reiterated in the 2008 Instruction *Dignitas personae*.[7]

Catholic theologians differ somewhat concerning the moral and practical responsibilities demanded by leaving the embryos in a frozen state (possibility 3), though they are unanimous in condemning the creating and freezing of embryos through IVF procedures. The most significant divide concerns the question of HET.[8]

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[2] IVF Babies Web site, http://www.ivfbabies.com.

[3] G. K. Chesterton, "Queen Victoria," in *Varied Types* (New York: Dodd, Mead and Company, 1903), 228.

[4] Jérôme Lejeune, *The Concentration Can: When Does Human Life Begin? An Eminent Geneticist Testifies* (San Francisco: Ignatius Press, 1992), 40.

[5] Congregation for the Doctrine of the Faith, *Donum vitae* (February 22, 1987), I.5.

[6] Ibid, original emphasis.

[7] Congregation for the Doctrine of the Faith, *Dignitas personae* (September 8, 2008), n. 16.

[8] CDF, *Donum vitae,* I.5 and *Dignitas personae,* n. 18. Catholic theologians differ with regard to the responsibilities demanded of the parents who conceive in vitro and freeze the resulting embryos. Rev. Peter F. Ryan, SJ, argues that not only do biological parents

Is Heterologous Embryonic Transfer Surrogacy?

One of the principal arguments against HET rests on the assertion that it amounts to a kind of surrogacy, which is condemned in both *Donum vitae* and *Dignitas personae*.[9] If this is indeed the case, then it would seem an unanswerable argument since, its proponents claim, surrogacy by definition means that a woman carries in her womb a child genetically not her own and this is precisely what occurs, and by definition must occur, in HET. However, this argument fails, as we will see, because it attributes to surrogacy a definition that neither document uses.

While both *Donum vitae* and *Dignitas personae* explicitly condemn surrogacy, the definition offered by *Donum vitae* is quite specific and need not necessarily include a condemnation of HET. Furthermore, the mention of HET in both documents is included in a section not specifically aimed at HET per se, but at procedures involving the generation of new human embryos apart from the conjugal union of spouses.

Donum vitae n. 3 condemns surrogacy in response to the question, "Is 'surrogate' motherhood morally licit?" It provides the following definition:

> a. The woman who carries in pregnacy an embryo implanted in her uterus and who is genetically a stranger to the embryo because it has been obtained

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have a responsibility to have their embryos implanted, but that the "rescue" of existing frozen embryos by women who are willing and able to gestate them ought to be a priority. See Peter F. Ryan, "Our Moral Obligation to the Embryo," in *Human Embryo Adoption: Biotechnology, Marriage, and the Right to Life*, ed. Thomas V. Berg and Edward J. Furton (Philadelphia: National Catholic Bioethics Center, 2006), 297–325. Rev. Tadeusz Pacholczyk rejects the claim that the moral obligation of the parents extends to implanting the frozen embryos, but he still asserts that it does extend to financially caring for the embryos in their frozen state by paying the cryogenics bill. See his June 2009 article in "Making Sense Out of Bioethics: What Should We Do With the Frozen Embryos?" on the Web site for The National Catholic Bioethics Center, http://www.ncbcenter.org/NetCommunity/PAge.aspx?pid=478. Nicholas Tonti-Filippini, who argues against embryo adoption, sees a moral problem in keeping embryos frozen and suggests thawing the embryos and returning them to their natural state, even though death would be inevitable. See his "The Embryo Rescue Debate," in *Human Embryo Adoption*, 69–114. Most Catholic theologians who oppose HET for the purpose of embryo adoption do so because they claim it violates one or more of the goods of marriage and is therefore illicit for any woman, married or unmarried, to engage in. Catholic theologians who argue in this way include Mary Geach, Rev. Tadeusz Pacholczyk, Nicholas Tonti-Filippini, and Christopher Oleson. Others argue that while embryo adoption may be licit for a married woman, it is illicit for an unmarried woman. This takes various forms, with some (such as John Berkman and Edward J. Furton) claiming that a woman who adopts an already existing embryo may do so licitly only if she intends to raise and care for the child once it is born, while others (such as William E. May) arguing that embryo adoption by HET is licit for any woman, married or unmarried, even if she does not intend to raise the child after it is born. For representative examples of the differences of opinion on this topic, refer to the contributions of the authors in *Human Embryo Adoption* and to Edward J. Furton, "Embryo Adoption Reconsidered," *National Catholic Bioethics Quarterly* 10.2 (Summer 2010): 329–347.

[9] CDF, *Donum vitae,* II.A.3 and *Dignitas personae*, n. 19.

through the union of the gametes of "donors." She carries the pregnancy with a pledge to surrender the baby once it is born to the party who com missioned or made the agreement for the pregnancy.

b. The woman who carries in pregnancy an embryo to whose procreation she has contributed the donation of her own ovum, fertilized through in semination with the sperm of a man other than her husband. She carries the pregnancy with a pledge to surrender the child once it is born to the party who commissioned or made the agreement for the pregnancy.

Does either of these two definitions of surrogacy apply to HET? Let us examine each individually.

It is indeed true that in HET, as the first definition states, the woman who carries the embryo is genetically a stranger to the child, but this is because the embryo "has been obtained through the union of the gametes of 'donors.'" *Donum vitae* implies that the principal moral difficulty is not the fact that the mother is genetically a stranger to the child but rather the manner in which she has become the carrier of the child. Certainly implicit in this definition is the fact that she has become the carrier of the embryo as a result of participation in and cooperation with IVF or artificial insemination—practices which the instruction has already condemned.

This first definition also identifies another moral problem. The woman carries the child not out of maternal love or a desire to give to the child the respect demanded by its human dignity, but because of a contractual agreement with the gamete donors. Such a scenario does not respect the dignity demanded by either the humanity of the child or the marital fidelity of the spouses who "donated" their gametes (assuming they were even married). The *Ethical and Religious Directives for Catholic Health Care Services* points to the contractual and commercial nature of surrogacy as illicit and cites the definition given by *Donum vitae*.[10]

Rev. Benedict Guevin, OSB, notes the tendency that exists in the field of reproductive technology "to make children 'objects' to satisfy one's desires to be a parent" and points out that most reproductive technology clinics primarily function as places of business.[11] However, the adoption of already generated and abandoned frozen embryos does not involve any of the conditions included in this first definition of surrogacy. It is entirely possible (and even probable, given the sheer number of abandoned embryos in the United States) that a woman adopting an already generated and abandoned embryo may not have participated in, cooperated with, or approved of the illicit union of the "donor" gametes in vitro. In addition, she may have in no way violated the dignity proper to the embryo by making it the subject of a contractual agreement. It is evident then that embryo adoption through HET does not automatically constitute an act of surrogacy.

[10] U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, 5th ed. (November 17, 2009), n. 42.

[11] Benedict M. Guevin, "Reproductive Technologies in Light of *Dignitas personae*," *National Catholic Bioethics Quarterly* 10.1 (Spring 2010): 57.

Can HET rightfully be called surrogacy according to the second definition given by *Donum vitae*? Like the first, this scenario also includes a contractual agreement to surrender the child once it is born. The woman carrying the child does so not out of maternal love, but because of a prearranged contract with those to whom she will give the child. Unlike the first scenario and definition though, this woman is not a genetic stranger to the child she carries in her womb. She has "contributed the donation of her own ovum, fertilized through insemination with the sperm of a man other than her husband." This can happen through fertilization in vitro with subsequent HET, artificial insemination and fertilization in vivo with donor sperm, or an act of fornication or adultery.

The moral act of the woman in this case is not to adopt and care for an abandoned child but to generate new human life with a man who is not her husband. In the preceding section, *Donum vitae* had already condemned the generation of human life apart from conjugal union, stating that "fertilization of a married woman with the sperm of a donor different from her husband and fertilization with the husband's sperm of an ovum not coming from his wife are morally illicit."[12] Thus this definition also does not apply to HET for the purpose of embryo adoption.

The reasoning *Donum vitae* gives in its response to the question "Is surrogate motherhood morally licit?" is also instructive:

> No, for the same reasons which lead one to reject heterologous artificial fertilization: for it is contrary to the unity of marriage and to the dignity of the procreation of the human person. Surrogate motherhood represents an objective failure to meet the obligations of maternal love, of conjugal fidelity and of responsible motherhood; it offends the dignity and the right of the child to be conceived, carried in the womb, brought into the world and brought up by his own parents; it sets up, to the detriment of families, a division between the physical, psychological and moral elements which constitute those families.[13]

Donum vitae identifies surrogacy not with HET as such but with heterologous artificial fertilization. The assumption here is that surrogacy always includes, as integral to its definition, the generation of (or cooperation in the generation of) new human embryos by IVF or artificial insemination. In fact, every mention of HET in *Donum vitae* is made in connection with IVF or artificial insemination. The instruction assumes that HET is taking place because one has cooperated already in IVF or artificial insemination.

Are the Moral Objects Different?

The dissimilarities between a woman who adopts a frozen embryo and a woman who is a surrogate are of crucial importance. While both women choose to carry an existing embryo, the surrogate does so for entirely different reasons. She does so, as E. Christian Brugger argues, "in order to fulfill the illicit purposes of the offending

[12] CDF, *Donum vitae*, II.A.2.

[13] Ibid., II.A.3.

person or couple … she chooses to carry out, to complete, their plan of action; she chooses to make herself part of their plan of action."[14] The adopting woman, on the other hand, has not cooperated in the illicit generation of the embryos, nor is she, according to the definitions offered by *Donum vitae*, a surrogate. The fact that both women choose the same technological process of having an embryo transferred from one location to another cannot be equated with the object of moral choice.

Brugger quotes Pope John Paul II in the encyclical *Veritatis splendor* who points out that by "object" of a moral act, "one cannot mean a process or an event of the merely physical order, to be assessed on the basis of its ability to bring about a given state of affairs in the outside world. Rather, that object is the proximate end of a deliberate decision which determines the act of willing on the part of the acting person."[15] In other words, the fact that both the surrogate and the adopting woman have an embryo transferred to their respective uteruses does not mean that they engage in the same moral act.

The surrogate chooses surrogacy as the completion of the illicit generation of human embryos outside of conjugal union; the adopting woman does not. It is clear then, that *Donum vitae*'s condemnation of HET only pertains to those cases in which HET constitutes the intended completion of the generation of new human embryos by artificial fertilization or when it falls under the specific definitions of surrogacy spelled out by the instruction. This is especially evident given the fact that the instruction never mentions embryo adoption by itself but only refers to HET insofar as it is connected to artificial fertilization.

What Does *Dignitas personae* Say?

Opponents of embryo adoption also point to n. 19 of *Dignitas personae*, which reaffirms *Donum vitae*'s condemnation of using existing embryos as "biological material" for research. The one mention of surrogacy in *Dignitas personae* repeats the definitions offered by *Donum vitae* and again links surrogacy with artificial heterologous procreation.[16] In addition, this brief paragraph in *Dignitas personae* does not refer to embryo adoption, but to "the proposal that these embryos could be put at the disposal of infertile couples as a *treatment for infertility*." Clearly *Dignitas personae* is condemning cooperation with the generation of new human embryos as the moral object of the acting woman, and not merely the physical act of embryo transfer.

This is made even clearer when considered along with the statement in the n. 18 of *Dignitas personae* that cryopreservation (and indeed even prenatal adoption) "presupposes [the embryos'] production in vitro." It also notes that using embryo transfer as a "treatment" for infertility could lead to other practical problems. This is not at all an outright condemnation of embryo transfer, but a call for much needed prudence and foresight.

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[14] E. Christian Brugger, "A Defense by Analogy of Heterologous Embryo Transfer," in *Human Embryo Adoption*, 213–214.

[15] John Paul II, *Veritatis splendor* (August 6, 1993), n. 78, quoted in ibid., 213.

[16] See footnote 38 in CDF, *Dignitas personae*, n. 19.

Dignitas personae does mention "prenatal adoption" and, interestingly, does not condemn it absolutely.[17] In fact, it calls the intention "praiseworthy with regard to the intention of respecting and defending human life." If prenatal embryo adoption were in itself illicit, the intention to do so would certainly not be referred to as "praiseworthy." By its own admission, *Dignitas personae* stops short of endorsing prenatal adoption as a licit option for resolving the frozen embryo dilemma, not because HET is in itself illicit, but because it "presents … various problems not dissimilar to those mentioned above." The document cites concerns of a "medical, psychological, and legal nature," indicating that the cause for caution is due, not to an intrinsic moral problem with prenatal embryo adoption, but rather the practical complications that might result from the practice.

In addition, the *possibility* exists that an endorsement of HET as a solution to the frozen embryo problem could be seen as an endorsement of IVF procedures, artificial fertilization, surrogacy, or even the destruction of embryos for research. Complicating matters is the fact that a woman who adopts an embryo would in all likelihood need to have the procedure carried out in a clinic that also participates in IVF. Catholic moral theologian William E. May (who supports embryo adoption) suggests that in order to avoid scandal, a woman who adopts an embryo "should take care to let it be known that she regards in vitro fertilization and surrogate mothering as intrinsically evil … and that her only interest is to protect an abandoned unborn baby's life."[18]

While the potential for grave scandal certainly exists, it does not mean that embryo adoption is illicit per se. On the contrary, as we have seen, every mention of HET in both *Donum vitae* and *Dignitas personae* is in reference to artificial fertilization and surrogacy and not to HET for the purpose of the adoption of already existing and abandoned frozen embryos. For these reasons, philosopher Christopher Tollefsen refers to the mention of embryo adoption by *Dignitas personae* as only a "so-called treatment" of the topic, since neither *Donum vitae* nor *Dignitas personae* actually addresses HET by itself, let alone HET for the purpose of embryo adoption. To cite either instruction in arguing against embryo adoption is to attribute to them a position that neither instruction takes and to attach to "surrogacy" a definition not in keeping with those offered by *Donum vitae* and used by *Dignitas personae*. Thus, Tollefsen's phrasing is not at all pejorative but simply meant to point out that neither instruction—as Tollefsen notes in his footnote to the phrase—addresses "embryo adoption in its full reality."[19]

Is This an Unresolvable Situation?

Critics of embryo adoption make what seems to be their strongest case by pointing to a passage in *Dignitas personae* that suggests that there is no licit way

[17] Ibid., n. 19.

[18] William E. May, *Catholic Bioethics and the Gift of Human Life*, 2nd ed. (Huntington, IN: Our Sunday Visitor, 2008), 101.

[19] See footnote 2 in Christopher Tollefsen, "Divine, Human, and Embryo Adoption: Some Criticisms of *Dignitas personae*," *National Catholic Bioethics Quarterly* 10.1 (Spring 2010): 76.

to resolve the frozen embryo problem. It states, "All things considered, it needs to be recognized that the thousands of abandoned embryos represent a *situation of injustice which in fact cannot be resolved*."[20] If embryo adoption does not, as has been shown, constitute surrogacy, and if it is not a violation of the child's right to be conceived in marriage or of the rights of spouses to become parents through each other, why then does the instruction not endorse it as a licit option for resolving the frozen embryo problem?

A consistent reading of both *Donum vitae* and *Dignitas personae* shows that both always link embryo transfer and even the notion of "becoming parents" to artificial fertilization and the conception of new human life. Both instructions assume cooperation with some form of surrogacy or IVF. It is clear, then, that neither instruction seeks to condemn HET and embryo adoption per se because, simply put, neither instruction even addresses the question of embryo adoption or HET apart from its connection to the illicit generation of human life through artificial fertilization or to surrogacy. Edward J. Furton also points out that a quotation from John Paul II in the same paragraph, stating that "there seems to be no morally licit solution regarding the human destiny of the thousands and thousands of 'frozen' embryos," cannot in fact refer to embryo adoption, since the quotation is from an address given in 1996, before the first successful embryo adoption.[21]

The widespread practice of IVF and a growing public utilitarian ethic mean that any attempt to resolve the frozen embryo problem must proceed carefully, since the lives of hundreds of thousands of innocent human beings are at stake. The risk of scandal is also ever present, and an endorsement of embryo adoption might not only be seen as an endorsement of IVF and surrogacy, but could actually lead to an *increase* in the practice of both, especially among Catholics.[22]

Whether the Church will endorse embryo adoption as a licit means of pursuing a resolution to the frozen embryo problem remains to be seen.[23] But what is clear from a careful reading of *Donum vitae* and *Dignitas personae* is that neither embryo adoption nor HET itself constitutes surrogacy or a violation of the rights of the already existing human lives currently in cryopreservation. On the contrary, adoption best recognizes and responds to the dignity demanded by these tiny human beings.

[20] CDF, *Dignitas personae*, n. 19, original emphasis.

[21] Edward J. Furton, "Embryo Adoption Reconsidered," *National Catholic Bioethics Quarterly* 10.2 (Summer 2010): 333.

[22] As a prudent solution to the problem of immoral cooperation with IVF and surrogacy, Furton has recommended that Catholic adoption agencies faithful to the moral teaching of the Church act as intermediaries, and he argues effectively that the obstacle of cooperation with the IVF industry is not insurmountable. See ibid., 345–347.

[23] *Dignitas personae* refers to the resolution of the problem as a "duty."

Catholic Hospitals, Institutional Review Boards, and Cooperation

Stephen Napier

Abstract. This paper addresses a certain lacuna in moral theological reflection. An institutional review board (IRB) reviews research on human subjects and so represents the institution's ethical review mechanism for research. The author argues that if an IRB approves a research project that is immoral, it thereby implicates the institution in formal cooperation. The author also argues that numerous ethical concerns are created by current research enterprises—concerns that extend beyond the "usual suspects" of embryonic stem cell research and research using cell lines of illicit origin. The author describes these more subtle issues and shows how IRBs at Catholic hospitals can navigate them. *National Catholic Bioethics Quarterly* 11.2 (Summer 2011): 257–266.

Catholic health care in this country is the second largest provider of charity care after the government. Many Catholic hospitals conduct research and do so in volumes. Although clinical ethics issues such as organ donation, end-of-life care, and principles governing the withholding or withdrawing of tube feeding have held center stage in Catholic ethical reflection, research ethics is an area of growing concern and ought to be the object of more extended inquiry.

This essay outlines and provides general guidance on ethical issues that can arise in research on human subjects. I limit the territory I cover to those issues that are of particular concern to Catholic hospitals and medical centers. I do this not to

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suggest that Catholic teaching is one perspective among many, or that such teaching is a list of arbitrary dos and don'ts that *only* Catholic hospitals are obligated to follow. Catholic moral teaching is rooted in *right reason* and aims to protect and promote basic human goods. As such, it is a universal ethic, capable of assent by any number of religious (and atheistic) perspectives. I limit myself to issues of concern to Catholic hospitals because the secular research ethics tradition has, for the most part, given accurate and comprehensive guidance on many other issues pertaining to research on human subjects. There is no reason to repeat such guidance and reflection here.

To motivate these issues, it is necessary to understand the basic structure of research on human subjects. There are basically two kinds of research involving human subjects: medical and socio-behavioral. If a researcher wants to do research on human subjects, there are several requirements to fulfill. First the researcher must submit a proposal to what is called an institutional review board. An IRB is a committee that reviews research on human subjects with an eye toward ethics. There is an elaborate regulatory framework that guides IRBs in their deliberations and enjoys wide consensus. The regulations outline very specific ethical requirements that research must meet. This includes specifying necessary elements for obtaining informed consent from subjects, requiring a favorable risk–benefit ratio for the research, and requiring valuable research that is well designed.

If the IRB approves the research, the researcher can then, and only then, begin to recruit subjects. Recruitment typically is from posters, referrals from other physicians, postings on the U.S. clinical trials registry at www.clinicaltrials.gov, or other public announcements. The researcher then conducts the work and typically has it reviewed by the IRB again roughly once a year or, for notably risky research, as often as stipulated by the IRB. The point is that the IRB stands as a gate through which almost every research project on human subjects must go. It is given the explicit task of protecting human subjects and providing ethical review. Its role and function within an organization and for the medical profession is both fundamental and ubiquitous with regard to research.

The kinds of issues Catholic IRBs face are often cooperation issues. Cooperation occurs when an institution (or person) assists in or contributes to the immoral act of another. The person cooperating is called the cooperator, the person performing the evil act is the principal agent. Analyzing cooperation cases involves prudentially applying the principle of cooperation, which aims to distinguish permissible from impermissible instances of cooperation. Not all cases of cooperation are impermissible; after all, many of our actions have cause-and-effect relations with other actions, and they with still other actions, some of which are immoral. We cannot control the cascade of effects some of our actions take, and are rightly not held culpable for those effects further downstream.

The basic idea is that the principle of cooperation is meant to give a detailed analysis of cooperation cases and whether or not the cooperator has done something immoral. For Catholic hospitals and their IRBs, the concern is with immoral aspects of certain studies. If a study is approved, would the approval amount to immoral cooperation with the evil aspects of the study? I wish to provide an answer to this

question that is specific to the evil aspects that can be present in certain studies. As we shall see, not all evil aspects are created equal.

An IRB, as noted, performs the function of a gatekeeper on research involving human subjects. With a vote to approve a research project, the IRB is saying that the researcher can *do* this research at *this* institution. Certain research activities will take place at this institution utilizing the resources this institution has to conduct the research. Because of what the IRB does, and the sequelae of its actions, the IRB acts *on behalf of* and not independent of the institution within which it functions. The proper organizational model for an IRB is that its members as a group represent the institution's moral commitment to ethical research. What the IRB approves is what the institution approves. The two are not separable, given the gatekeeper role of the IRB with regard to which research projects will be conducted at the institution. And this is why, when an IRB approves a study with evil aspects, the institution cooperates in that evil.

Consent and Contraception: Informing versus Requiring

We can now address specific ethical issues that IRBs may confront. The first issue concerns trials investigating a new drug or studying an added indication for an existing drug. For most drug trials, there is a requirement that female subjects of child-bearing age (hereafter female subjects) cannot become pregnant.[1] How they are told not to become pregnant is the issue. For example, if, as a condition for being involved in the study, female subjects are required to use artificial contraceptives, then trouble looms. This is not to say that an IRB is *necessarily* cooperating in evil when it approves a study with consent documents that include language requiring the use of artificial contraceptives. Let us consider some examples from possible consent documents:[2]

> (P1) Female subjects of child-bearing potential are asked not to become pregnant while they are in this study.

P1 is benign because it does not recommend the use of contraceptives. It simply informs the subject that she cannot become pregnant. How she decides not to become pregnant is up to her, not the researcher and certainly not the IRB. We may even add to P1 a recommendation for abstinence such as the following:

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[1]The drugs in question fall into three different categories pertaining to their potential risk to developing human fetuses: Category B drugs have no evidence of risk in human fetuses, but evidence in animals; Category C drugs pose risks to human fetuses that cannot be ruled out; and Category D drugs pose risks to human fetuses that are known. See Food and Drug Administration, "Labeling and Prescription Drug Advertising: Content and Format for Labeling for Human Prescription Drugs," *Federal Register* 44.124 (June 26, 1979): 37434–37467.

[2]None of the examples in this paper are derived from my experience on IRBs. They are imagined cases aimed at generating principled moral guidance.

> (P1′) Female subjects of child-bearing potential are asked not to become pregnant while they are in this study. Abstinence is the most effective method for not becoming pregnant.

Now (P1′) is obviously true and conforms to right reason with regard to proper ways of avoiding pregnancy. It does not treat subjects as bundles of uncontrollable sexual urges but as persons capable of rational choice—after all, the researcher needs to suppose they have this capacity, for they are giving *consent* to research that poses risks to themselves. The researcher must assume that he is recruiting a rational subject capable of informed choice.[3] The general point in regard to P1 and P1′ is that the researcher, in the capacity of informing the subject, can disclose the risks of the drug on a developing fetus, require that the female subject not become pregnant, and *recommend* the most effective way of not becoming pregnant (i.e., abstinence).

In spite of how reasonable this basic line of thought is, it is rarely seen. Rather, researchers and the sponsors of such research (those who fund it) typically recommend or even require the use of artificial contraceptives, and informed consent documents typically require a two-barrier method to avoid any drug interaction with oral contraceptive pills. Since the devil is in the details, consider some examples:

> (P2a) If you are a woman of child-bearing potential (or a man who may father a child) and you consent to being in this study, you must agree not to become pregnant (or father a child) during [specify timeframe]. The only way to be certain that you are not pregnant (or certain that you have not fathered a child) is to abstain from sexual intercourse. If you choose not to abstain, you must agree to use a two-barrier method of contraception (e.g., diaphragm plus condom).[4]

> (P2b) If you are a woman of child-bearing potential (or a man who may father a child) and you consent to being in this study, you must agree not to become pregnant (or father a child) during [specify timeframe]. You must agree to use a two-barrier method of contraception (e.g., diaphragm plus condom).

Both P2a and P2b require that subjects use contraceptives while in the study, although the P2a requirement is conditional. Before I address the question of whether this conditional requirement exculpates, let me note my basic point in giving these examples: the requirement that the subject use contraceptives in order to be involved in the research endorses and encourages contraceptive acts. This is immoral, and a Catholic hospital whose IRB approved such a study would likewise be approving

[3] There are complications here regarding studies on female psychiatric patients for whom there cannot be an assumption of rationality, especially in regard to choosing abstinence. This complication is addressed below.

[4] Adapted from *A Catholic Guide to Ethical Clinical Research*, by the Catholic Medical Association and National Catholic Bioethics Center (Philadelphia: CMA and NCBC, 2008), 36. The author highly recommends this publication to researchers wishing to explore numerous other aspects of research ethics.

the use of contraceptives. The Catholic hospital would thus be implicated in formal cooperation.

One may question whether making the requirement conditional exculpates the researcher from mandating the use of contraceptives. One line of argument points out that the researcher is actually *not* requiring the use of contraceptives, but the subject is. If the subject herself chooses to engage in sexual intercourse, then she fulfills the condition that, if satisfied, requires the use of contraceptives. The choice to use contraceptives is not the researcher's but the subject's, because the need to use contraceptives applies only to a decision made *by the subject*. In some sense, whether the subject needs to use contraceptives is up to the subject. But now it looks as if the reasoning that permitted P1 is duplicable in P2, whether to use contraceptives is "up to the subject" and is not an essential aspect of the study.

Although this is an interesting argument, I do not think it exculpates. It is certainly true that the researcher in the case of P2a requires the use of contraceptives *if* the subject chooses to have intercourse while in the study. But one must distinguish here between what the researcher requires and what the subject chooses. By the subject's own choice, she satisfies a sufficient condition for using contraceptives, as indicated in the consent form; but this condition itself is set not by the subject but by the researcher. After all, it is obvious that the subject did not choose the conditional requirement itself. All she does is satisfy a condition of the requirement, the requirement itself being set by the researcher. Because it is the researcher who sets the requirement, the *researcher* is requiring the use of contraceptives if the subject chooses not to abstain.

When I say to my daughter, "If you are out past midnight, you must call me," I am requiring her to call me in the event that she chooses to stay out past midnight. If my daughter calls me at 12:01 a.m. and I ask, "Why are you calling me?" she will respond correctly, albeit confusedly, "Because you *wanted* me to!" It is up to her whether to stay out past midnight or not, but it is not up to her to call me in the event that she does stay out past midnight. I place *that* requirement on her to call me.

The same line of thought applies to the researcher who includes the language about contraception in the consent form. Although it is up to the subject whether to choose to abstain from *intercourse* or not, it is not up to the subject to *use contraceptives* in the event of not abstaining. Another way of putting this point is to place ourselves in the researcher's shoes and ask, assuming we believe that contraception is wrong, whether we would accept such language in our protocol. If we really thought that contraceptive acts were intrinsically evil, we would not say, "You must use a two-barrier method of contraception." That would not be something we would require of any of our subjects. The researcher, then, is clearly not exculpated from requiring that a subset of subjects use contraceptives. If all the subjects chose to abstain, would the researcher still have done something wrong? Most of us would say he got lucky. Because we would say that he avoided immoral cooperation only by luck indicates something about what is being required in the consent. And what is being required manifests his outright approval of contraceptive acts.

We can now see why a Catholic IRB that approves a study with something like the consent language of P2a or P2b is formally cooperating in contraceptive acts. In

approving the study, the IRB is approving all aspects of it as meeting basic ethical criteria. In doing so, it is approving the conditional requirement that subjects use contraceptives if they choose to have intercourse during the study.[5]

IRBs may also come across hybrid versions of P1 and P2 whereby the consent language informs subjects that they ought not to get pregnant or father a child and, instead of explicitly endorsing artificial contraceptives, says that potential subjects should *consult with the study doctor* on the most reliable methods of preventing pregnancy or fathering a child. Although artificial contraceptives are not explicitly required, the ethical worry with this hybrid version is that we can readily anticipate that the study doctor will recommend barrier methods or other artificial contraceptives. Is knowing this enough to implicate the Catholic IRB in formal cooperation?

There are alternative considerations in this regard. First, if the consent language requires subjects to use artificial contraceptives in order to be in the study, not mentioning this in the consent form is a grave informed-consent issue. Alternatively, assuming that the consent language meets regulatory and ethical standards for informed consent, the IRB can justifiably infer that artificial contraceptives are not required and may approve the study—assuming that other ethical criteria are met. This is the case even if the IRB knows that the researcher will recommend the use of artificial contraceptives to at least some subjects. The reason the study would still be approvable by the IRB is that the IRB does not have ethical jurisdiction over what the researcher says to subjects. Protection of human subjects is a shared and coordinated activity between researcher, sponsor (e.g., drug or device company), and IRB. The IRB has limited but important ethical duties; however, policing specific conversations between the researcher and the subject is not one of them. The IRB approves protocols, and it can suspend a study if there is a deviation from the protocol. But if artificial contraceptives are not required by a protocol, and it is known that the researcher will recommend them to some subjects, this is still not a protocol deviation and therefore not for the IRB to police or correct.[6] Therefore, a Catholic IRB can approve a consent procedure that delegates the responsibility for advising

[5]I am not addressing in this article why contraceptive acts are intrinsically immoral. However, a good case is made for why such conditional requirements should not be in consents anyway based on a respect for the person's own reasoning capacities. For a clear and persuasive articulation of this argument, see Terry M. VandenBosch, Becky G. Ward, and Debra Mattison, "A Reappraisal of Female Adolescent Participation in Drug Clinical Trials," *IRB: Ethics and Human Research* 21.1 (January–February 1999): 1–5.

[6]The principle I am relying on here is that the IRB approves what is indicated in the protocol. If the use of artificial contraceptives is not required by the protocol, the IRB approval pretermits, or "passes over," any discussion about contraceptives that may take place. Since the approval pretermits, or does not cover, any endorsement of artificial contraceptives, there is no formal cooperation. ("Pretermit" derives from the word "preterition," which is the Calvinist doctrine whereby God passes over or neglects determining who the damned are. Given the Calvinist understanding of predestination, preterition is an attempt to avoid a serious problem of evil.)

subjects on how to avoid pregnancy to the researcher. Of course, if artificial contraceptives are required, then the arguments against P2 above are apropos.

What about studies on psychiatric patients in which it can be presumed that the subjects do not and, because of their psychiatric problem, cannot be expected to abstain from sexual intercourse while in the study? What should informed-consent documents communicate about the risks to the fetus and the means by which to prevent such risks? Suppose the proposed research project aims to test a hormonal intervention (say, synthetic testosterone) on subjects with a peculiar endocrine disorder. It is known that hypersexual activity disorder is strongly associated with endocrine dysfunction,[7] and because of this, a subset of the subject population is expected to have hypersexual activity disorder. Or consider a study enrolling mentally disabled adults among whom there is a high incidence of hypersexual activity disorder.[8] In deliberations about such a so-called hard case, it is important to be clear at the outset about the features of the case that generate the ethical problem.

In such cases, the feature generating the ethical problem is that the study intervention (i.e., a drug) can pose serious risks to a developing fetus but at the same time holds out theoretical benefit to the subjects. Notice that the feature generating the problem is *not* "avoiding pregnancy" but rather "not giving the drug to a pregnant woman." If we are first clear about what generates the moral issue, a solution is not far from view. In many studies in which a drug's effects pose a serious risk to a developing fetus, a pregnancy test is done prior to any administration of the drug. This measure would go a long way toward preventing the key problem, namely, administration of the drug to a pregnant woman. Although it is not an airtight solution, it respects the dignity of the human person by not requiring her (or him) to perform contraceptive acts—assuming they would be performing such acts at all.[9]

Vigilance should be exercised for such subject populations, among whom sexual activity is prevalent and decision making capacity is compromised, to ensure that they behave in a way consistent with the demands of the protocol. The vigilance necessary to ensure that contraceptives would be used properly under such a protocol would be better directed toward ensuring that the subjects behave in ways that are respectful of their bodies, such as abstinence. If enough vigilance can be exercised to ensure that these subjects use contraceptives properly, which would be necessary if a two-barrier method were required, then such vigilance can be devoted instead to ensuring that subjects behave in a way respectful of their bodies.

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[7] See Richard B. Krueger and Megan S. Kaplan, "Disorders of Sexual Impulse Control in Neuropsychiatric Conditions," *Seminars in Clinical Neuropsychiatry* 5.4 (October 2000): 266–267.

[8] See B. A. Myers, "Treatment of Sexual Offenses by Persons with Development Disabilities," *American Journal on Mental Retardation* 95.5 (March 1991): 563–569.

[9] For an argument that these are not contraceptive acts, see Stephen Napier, "Contraception for the Mentally Disabled: A Contraceptive Act?" *Linacre Quarterly* 77.3 (August 2010): 280–307.

A general guide to resolving hard cases is to avoid easy solutions. By this I mean that the morally correct solution to "hard cases," such as cases of pregnancy following rape or cases cited by proponents of euthanasia, typically requires a greater sacrifice on the part of a caregiver or family member. Once we acknowledge that greater sacrifice and moral virtue are required to care properly for those under our responsibility, many ethical dilemmas are deflated and vanish. This is no less true for drug sponsors who expect to enroll subjects with hypersexual activity disorder and limited decision making abilities in clinical trials.

The take-home lesson about contraceptive language in consent forms is that such language cannot *require* the use of contraceptives by subjects while they are in the study. Ideally, the language will simply state that pregnancy should be avoided and that abstinence is the most reliable way to avoid it. It is permissible, but not ideal, to require that subjects not become pregnant and then list the various methods by which pregnancy can be avoided. In listing effective methods of pregnancy prevention, the researcher is performing the function of educator on what means are available but is not recommending or requiring the use of any one method. Informing the subjects about contraceptive methods and their effectiveness is permissible and provides information that is publicly available. It is no different from, say, a health science teacher describing what contraceptive methods exist and the effectiveness of each. Education per se does not contribute to or assist in the evil act of another, and therefore an IRB that approves studies with such language would not be implicated in immoral cooperation.[10]

HIV Reduction Studies: Education versus Promotion

Studies in which the procedures themselves are morally questionable also pose a risk of immoral cooperation for Catholic IRBs. In this category, I am considering

[10]There are exceptions to this analysis of education vis-à-vis cooperation. Suppose a woman shows up at a pregnancy counseling center (like Birthright). After receiving counseling, the woman remains unconvinced that keeping her child is the right action to take. She tells the counselor of her wish to procure an abortion. If the counselor "educates" her on which clinics perform abortions (information that is publicly available), the counselor has still done something seriously wrong. The feature of this case that makes it an instance of immoral cooperation is that the principal agent (the pregnant woman) has elected an end (i.e., chosen an evil end) and has informed the putative cooperator of this choice. Knowing that such a choice has been made, the cooperator, in providing information on where abortions clinics are, is contributing to the sequence of means ending in an abhorrent act. The counselor is now in a position of knowingly providing assistance in or contributing to the performance of the evil act. And this satisfies the conditions for cooperating in evil. Of course, there are complexities here. If the counselor diverts the client to an abortion clinic that uses an ultrasound and plays back the fetal heartbeat, a clinic in which many women change their minds, then the counselor could be choosing to convert the client through a "last ditch" effort. (Thanks to Deacon Alvin Clay, of the Archdiocese of Philadelphia, for pointing out this possibility.) This would not amount to immoral cooperation.

studies such as HIV reduction studies among homosexual or drug-using populations. Such studies could involve instruction on how to use condoms or promote other lewd ways of experiencing sexual arousal that do not involve penetration, such as anilingus. Or they could involve dispensing clean syringes for the very purpose of illicit drug use. Studies of these sorts illustrate how education about *x* can turn into immoral cooperation. To see this requires us to consider the very reason for research on human subjects.

Any study must hold out a prospect of benefit from the knowledge gained for the subjects involved or at least for future populations. The whole premise behind a study is to see if *x* (where *x* represents some intervention, device, or drug) works in addressing *p* (where *p* is some pathology or disease). HIV reduction studies can involve interventions that educate about the use of condoms or about how to perform lewd sexual acts. These interventions would not be entertained as study procedures unless they were expected to work in reducing the transmission of HIV. But they would work only if employed or practiced by the subjects. The study procedure, then, is not merely education; rather, it is promotion of condom use or of alternative sexual activity, because what the study is seeking is information about whether using condoms, performing other sexual acts, or using clean syringes works to reduce HIV infection rates.

Of course, not all HIV reduction studies should be precluded from review by Catholic IRBs. One needs to look at the design and procedures used in the protocol. Some protocols truly test only an *educational* intervention that does not promote illicit activities. The distinction between education and promotion can be determined fairly easily. A well-designed study will be clear about whether it is testing an intervention consisting of *education* about *x* or *promotion* of *x*. The two interventions are quite different conceptually and ought to be distinguished practically so as to yield reliable data. If the IRB is confused about whether illicit activities are being promoted *qua* study interventions, then the study is not well designed and should be tabled.

Future Risks

There is another category of studies in which the study procedures are morally neutral but the *use* that can or will be made of them is immoral. For example, an IRB could come across an "availability" study aiming to discover whether access to abortion is as easy for low-income women as for higher-income women. Although the information itself is morally neutral, it could easily be used to justify public policies that expand access to abortion among low-income women.

Here it is important to attend to the reason for the study as outlined in the "background" section of the study protocol. If the research is well motivated, it will be clear not only *what* information is lacking, given the present state of research, but also *why* getting that information is important. It is the answer to this latter question that will indicate the intentions of the researcher. As in the previous paragraph, if the importance of the study is not well articulated, then it is not a well-motivated study and should be tabled for lack of scientific benefit. Data per se are not beneficial; they must be linked to an important scientific question. If an IRB is concerned about the use to which information may be used, it should ask why the study is being done.

What is so important about getting such data? A good answer will typically point to, if not explicitly state, the use intended for the data.

In this article I have outlined three areas of ethical concern for Catholic IRBs. I have explored various ways in which ethical issues can be avoided or deflated, as in the latter two cases. It is important for Catholic hospitals at which research takes place to be aware of these areas and know how to handle them, to protect their institutions from cooperating in evil and to ensure reliable research that respects the dignity of the human subjects.