Catholic Hospitals, Institutional Review Boards, and Cooperation

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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.