Proxy Consent to Human Experimentation

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A cardinal principle of medical ethics is that calling for free and informed consent in all types of experimental situations in which a human being is the subject of the experimentation. This principle was eloquently affirmed in the articles of the Nuremberg Code, in the 1964 Declaration of Helsinki of the World Health Organization, in the code of the American Medical Association adopted at the 1966 convention, and in the “Ethical and Religious Directives for Catholic Hospitals.” It is a principle at the heart of traditional Jewish and Christian medical ethics, and is a principle time and again affirmed by the magisterium of the Roman Catholic Church. It is, as Paul Ramsey terms it, a primary “canon of loyalty” demanding the allegiance of every human being in every situation in which one human being is the experimenter and the other his “co-adventurer” in the experiment.

At the heart of this principle, I believe, is the belief that human beings are beings of moral worth. By a being of moral worth I mean an entity that is the subject of inalienable rights that are to be recognized by other entities capable of recognizing rights and that demand legal protection by society. By a being of moral worth I mean an entity that is valuable, precious, irreplaceable just because it exists. By a being of moral worth I mean a being that cannot and must not be considered simply as a part related to some larger whole.

This is not the place to show the truth of this belief that, in my judgment, informs the principle of free and informed consent. Still it is instructive to observe that recently the philosopher Roger Wertheimer expressed the same point by referring to what he termed “Standard Belief,” that is, the belief that “being human has moral cachet; viz., a human being has human status in virtue of being a human being (and thus each human being has human status).” According to this Standard Belief membership in the human species is a morally significant fact, and because being human has “moral cachet” it follows, as Ramsey has so simply
yet eloquently put it, that “no man is good enough to experiment upon another without his consent.”

Yet there are instances—and these are by no means rare—when it is impossible to obtain an adequately informed and free consent from the person who is himself to be the subject of the experiment. What can be done, what ought to be done, in such cases when the subject, whether by reason of age, mental infirmity, or physical condition, is unable to give consent in his or her own behalf?

There is no serious debate among authorities, whether medical, legal, or moral, in cases when the experiment in question is designed to secure some benefit for the person who is to be its subject, when the experiment is “therapeutic” at least in a broad sense. In cases of this kind consent to the experiment can be given by others (parents, guardians, etc.) in behalf of persons incapable of giving consent for themselves. Writers speak in this connection of “proxy” or “presumptive” or “vicarious” consent, and there is unanimity that in therapeutic situations such “proxy” consent is morally justifiable.

Some Reflections on the Debate

But there is serious debate, at least among moral authorities, about proxy consent in the non-therapeutic situation. Richard McCormick, the noted Jesuit moral theologian currently serving as Kennedy Professor of Christian Ethics at the Center for Bioethics of the Kennedy Institute, recently observed that here there are “two identifiable schools of (moral) thought . . . The first is associated with Paul Ramsey and is supported by William E. May. The second is the position of [Charles] Curran, [Thomas] O’Donnell, and myself.” My purpose here is to offer some reflections on this debate in the hope that by doing so the deeply significant human values at stake will be clarified. I propose (1) to outline the position taken by Ramsey early in the debate; (2) to summarize the position advocated by McCormick; (3) to note the objections that I originally raised to this position; (4) to look at the reply to these objections given by McCormick; and (5) to present some new reflections.

In his Patient as Person Ramsey first noted that some forms of nontherapeutic experimentation might not, in fact, “harm” a child (or other human subject incapable of giving consent in his own behalf). Yet he argued that nontherapeutic experimentations—that is, experimentations not intended to be of benefit to the subject but rather intended to advance scientific knowledge or benefit persons other than the experimental subject—constitute “offensive touching” and thus “wrong” the subject. In developing his position Ramsey wrote as follows:
To attempt to consent for a child to be made an experimental subject is to treat a child as not a child. It is to treat him as if he were an adult person who has consented to become a joint adventurer in the common cause of medical research. If the grounds for this are alleged to be the presumptive or implied consent of the child, this must simply be characterized as a violent and a false presumption. Nontherapeutic, non-diagnostic experimentation involving human subjects must be based on true consent if it is to proceed as a human enterprise. No child or adult incompetent can choose to become a participating member of medical undertakings, and no one else on earth should decide to subject these people to investigations having no relation to their own treatment. That is a canon of loyalty to them. This they claim of us simply by being a human child or incompetent. When he is grown, the child may put away childish things and become a true volunteer. This is the meaning of being a volunteer; that a man enter and establish a consensual relation in some joint venture for medical progress.15

In Patient as Person Ramsey also observed that when we use the term "proxy consent" to designate the human act involved in decisions to authorize therapeutic experiments on children and incompetent adults, the "consent" involved is in some degree a "false" consent. He noted that to construe or presume consent in such cases we are by no means doing violence to the human being in whose behalf the "consent" is given, but he insisted that there was a degree of falsehood in using this expression.16 His intent, I believe, was that it is simply false to say that a child or incompetent adult is himself "consenting" to the therapeutic experimentation.

In his original essay on "Proxy Consent in the Experimental Situation" McCormick first sought to find in the moral theory of such philosophers and theologians as J. de Finance, G. de Broglie, G. Grisez, and John Finnis the ultimate justification of "proxy consent" in the therapeutic situation. The heart of his argument, as he has himself recently restated it, is as follows: "if we analyze proxy consent where it is accepted as legitimate—scil. in the therapeutic situation—we will see that parental consent is morally legitimate because, life and health being goods of the child, he would choose them because he ought to choose the good of life. In other words, proxy consent [in the therapeutic situation] is morally valid precisely insofar as it is a reasonable presumption of the child's wishes, a construction of what the child would wish could he do so. The child would so choose because he ought to do so, life and health being goods definitive of his flourishing."17

In other words, McCormick sees the ultimate justification of "proxy consent" in the therapeutic situation in the reasonableness of the presumption that the child or other incompetent would himself consent to the experiment if he could, and that he would consent because he ought to do so.

McCormick then applies this
reasoning to the nontherapeutic situation. Here he is at pains to reject any "utilitarian evaluation of children's lives that would submit their integrity to a quantity-of-benefits calculus far beyond any legitimately constructed consent." Yet McCormick holds that there might be some types of nontherapeutic situations in which the consent of the child or other incompetent could be reasonably presumed, if one accepts the analysis that he has provided of the rationale behind justifiable proxy consent in the therapeutic situation. Here his position, as recently summarized by McCormick himself, can be expressed in this way:

Once proxy consent in the therapeutic situation is analyzed in this way, the question occurs: are there other things that the child ought, as a human being, to choose precisely because and insofar as they are goods definitive of his well-being? As an answer to this question I have suggested that there are things we ought to do for others simply because we are members of the human community. These are not precisely works of charity or supererogation (beyond what is required of all of us) but our personal bearing of our share that all may prosper. They involve no discernible risk, discomfort or inconvenience, yet promise genuine hope for general benefit. In summary, if it can be argued that it is a good for all of us to share in these experiments, and hence that we ought to do so (social justice), then a presumption of consent where children are involved is reasonable, and proxy consent becomes legitimate.20

In other words McCormick first argues that there are moral obligations that all of us ("we") have as members of the human community to contribute to the "general benefit," i.e., the common good when doing so would entail no "discernible risk, discomfort, or inconvenience." Since children and other incompetents are members of the human community, one could then reasonably presume that they would of themselves, if they could, choose to participate in nontherapeutic experiments, precisely because the child or other incompetent "ought to want this not because it is in any way for his own medical good, but because it is not (a) in any realistic way to his harm and (b) represents a potentially great benefit to others."21

Justifying Proxy Consent

It is very important to note, I believe, that McCormick's justification of proxy consent to non-therapeutic experiments on children and other incompetents that involve no discernible or minimal risk is inherently dependent for its validity on his analysis of the rationale justifying proxy consent in the therapeutic situation. In my original essay on this subject this was the precise point that I sought to stress. With Ramsey I believe that the term "consent," when applied to those instances when others give consent to an experiment on a human being who is himself incapable of giving consent, is in some degree false. I therefore argued that the justification of "proxy consent" in the therapeutic situation in no way

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required us to "construct" the consent of the child or other incompetent by inferring that he would, if he could, consent to the experiment precisely because he ought to do so if he is to manifest the love for the good of life and health that is required of human subjects. Rather I argued that the basic justification for "proxy consent" in the therapeutic situation was grounded in the moral obligations incumbent on parents and other adult members of the human community to do what they could to protect the real goods of life and health when these were being imperiled in human beings who were themselves incapable of protecting these goods in themselves. In articulating my justification for proxy consent in the therapeutic situation I appealed to the Kew Gardens Principle as articulated by Jon Gunneman, Charles Powers, and John Simon in their The Ethical Investor. According to this principle, we (that is, responsible adult human beings who are properly speaking moral beings or moral agents) have an obligation to do something in behalf of our fellow human beings when they are in need of help, when we are aware of the peril they are in (proximity), when we have some capacity to come to their assistance (capability), and when they will surely suffer or be deprived of some basic human good unless we take effective action (last resort).

Here I want to note that I could have, and perhaps ought to have, appealed to the moral theory of Germain Grisez to justify "proxy consent" in the therapeutic situation inasmuch as it was to this theory that McCormick appealed in articulating his own position. Hence I now wish to call attention to this theory and the way it ought to be applied, in my judgment, to the issue of proxy consent in the therapeutic situation.

According to the moral theory of Germain Grisez and the other writers to whom McCormick appeals, the human good is pluri-form, that is, it consists of a set of real goods constitutive of what we can call the whole or total human good, and these goods are real and not merely apparent because they are inherently related to real needs rooted in our being. Among these goods are life and health. Neither life nor health or any of the basic human goods is the supreme good or summum bonum, but each is a real good of real human beings and each, as known, functions as a principle of practical reason or what we could call a principle of intelligent behavior.

There are several ways, according to this theory, in which the basic human goods that give rise to affirmative moral principles bind us. In his articulation of this theory Grisez distinguishes five modes of obligation. I shall note them here and simply point out that the third mode of obligation that he distinguishes is precisely the mode of obligation at stake in the therapeutic situation when the human subject is himself in-
capable of giving consent. According to Grisez the basic modes of obligation are the following:

In the first place, all of these goods bind us at least to this, that we take them into account. In our practical reasoning, we must have a permanent sensitivity to the essential goods to which primary principles direct. An attitude of simple disregard for any one of them reveals that we have set ourselves against it. Therefore, such an attitude is incompatible with our basic obligation to pursue and to act for it.

In the second place, everyone of the goods demands of us that, when we can do so as easily as not, we avoid acting in ways which inhibit its realization and prefer ways of acting which contribute to its realization. This principle never can be applied legalistically, but nevertheless its use is quite common in practice in ordinary moral arguments.

... In the third place, every one of the goods demands of us that we make an effort on its behalf when its significant realization in some person is in extreme peril. This obligation ... frequently binds with great force ... This type of obligation binds in degrees varying with the seriousness of the stake, the immediacy of the peril, and the opportunity we and others have for giving aid.

In the fourth place, every one of the goods demands of us that we do not act directly against its realization.

Still another, the fifth way, in which the values establish obligations is that each one of them demands of us that we keep our engagements with it. We do not have a general obligation to seek out opportunities for promoting every one of the goods. But we should pursue something good, and each person according to his individual aptitude must choose the values he will try to promote.

It ought to be obvious, I believe, that the third mode of obligation is the mode of obligation at stake in situations when so-called "proxy consent" is given in the therapeutic situation. It is simply a way of stating the "Kew Gardens Principle" adopting the moral theory of Germain Grisez, the moral theory to which McCormick appealed in articulating his position.

To summarize at this point, I believe that the basic reason why it is morally legitimate for a parent or other adult to "consent" to allow his child or other incompetent human being to participate in a therapeutic experiment is simply that the consent in such cases is an exercise of proper moral responsibility by a moral agent of the obligation that he has to promote the good of another human being when this good is imperiled and he has the capacity of doing something about it. There is no need for him to construct the child's wishes or to presume that the child would of himself consent to the procedure if he could because of any moral obligation on his part to do so.

I objected to the position of McCormick inasmuch as I thought that his analysis of the justification for proxy consent in the therapeutic situation was inaccurate and, a fortiori, that his analysis of the justification for
proxy consent in the nontherapeutic situation was erroneous. I claimed that his position requires one to treat a child or other incompetent moral individual as a moral agent, something that a child or other incompetent, simply by being a child or incompetent, certainly is not. 29

In commenting on the objections brought against his position McCormick made two points. His first was that the position he articulated does not “necessarily regard the infant as a moral agent. Nor need it,” he wrote, “imply that he has obligations. It need only suggest that what it is reasonable and legitimate to do experimentally with youngsters might be constructed off what others who are moral agents ought as humans to do; for though they are not yet moral agents, infants are humans in the fullest sense.”30

As far as the first element in McCormick’s first point is concerned—namely that his position need not imply that an infant has moral obligations—it seems to me that in articulating his position he not only implied that the infant has moral obligations but asserted that he did. For he wrote: “proxy consent is morally valid precisely insofar as it is a reasonable presumption of the child’s wishes, a construction of what the child would wish could he do so. The child would so choose because he ought to do so.”31 If this is not to presume or infer or construct moral obligations existing in the child, then I have difficulty in grasping what it is.

Further Observations
With respect to McCormick’s claim that his position “need only suggest that what is reasonable and legitimate to do experimentally with youngsters might be constructed off what others who are moral agents ought as humans to do; for though they are not yet moral agents, infants are humans in the fullest sense” I would like to offer the following observations.

With McCormick I believe that infants and adult incompetents are humans in the fullest sense. But I believe that we need to make some distinctions when we speak of what we as humans ought to do. I believe that I do not, precisely as a human being, as a member of the human species, have any moral obligations. Yet I do believe that I am, precisely as member of the human species, as a human being, a being of moral worth, an image of God, a being of whom it is written “Does a woman forget her baby at the breast, or fail to cherish the son of her womb? Yet even if she forgets, I will never forget you. See, I have branded you on the palms of my hands” (Is 49:15-16). As a human being, as a member of the human species, I am radically capable of becoming a moral agent, a being with moral obligations, but in order for me to become such an entity I need help of the human community. Let me now try to explain why,

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and why I believe this character of our existence is so central to the issue of proxy consent in the nontherapeutic situation.

No one in this room—no human being anywhere—was a moral being or moral agent at birth. No one in this room, no human being anywhere, was a person or personal subject at birth, if by person or personal subject one means a self-conscious entity aware of itself as a self, as an enduring subject of experiences, capable of communicating with other persons, other selves, and capable of distinguishing between is and ought. Empirical evidence is relevant and determinative here. There have been, for example, recorded instances of feral or "wolf" children, that is, human infants separated from a human community quite early in their lives who were then reared by animals such as wolves or bears. When these human offspring—beings certainly human by reason of their membership in the human species and in my judgment (and in Christian faith) infinitely precious beings imaging the living God—were found by other human beings and brought back into the human community, it was evident that they did not have any realization or awareness of themselves as selves. They totally lacked the concept of selfhood—indeed they were completely incapable of entertaining any concepts. They were, in brief, quite oblivious to their own identity as human beings and obviously they were in no way bearers of moral obligations.

What this fact (and others like it) does, I suggest, is to make us acutely conscious of the social solidarity of human existence. They show us that human existence, as a personal existence, is inescapably and necessarily a co-existence, or to use a biblical expression, that human existence is convental in character. To be human in the sense that to be human means being personal and being a self aware of its responsibilities is to exist with other human beings. But for us to exist with other human beings we must first be granted leave by them to exist with them. Personhood, in other words, is a gift. It is, in a very real sense and in one respect, a gift that each one of us receives from other human beings (although ultimately God is the source of our personhood). It is a gift that we receive, directly and immediately, from the parents who conceived us in an act that was at the very same time, one hopes, an act expressive of the love they had for one another, and it is a gift that we continually are called upon to bestow on one another. My being me depends, in a very real way, on your being you and allowing me to be me. An indispensable prerequisite for our becoming persons is the help of the human community. We must first be recognized by that community for what we are, namely beings of moral worth, if we are to grow into personhood.

Perhaps I could express some-
what more clearly what I have in mind if I reformulate somewhat the strikingly perceptive formulation of the Golden Rule suggested by Roger Wertheimer in the essay to which I referred earlier. I submit the following: You, a moral being (i.e., a personal subject capable of rational reflection and of exercising moral responsibility and of being the bearer of moral obligations) are to do unto others (i.e., other members of the human species, other beings of moral worth) as you, a member of the human species and a being of moral worth, would have others (i.e., other moral beings, other personal subjects capable of rational reflection and of exercising moral responsibility and of being the bearers of moral obligations) do unto you, a member of the human species, a being of moral worth.

Apply this now to the instances when "proxy consent" is at stake. In the therapeutic situation those human beings who have become moral agents and bearers of moral obligations (and have become so because they have at least been allowed to be and have been in some way recognized for they really are by the human community) find themselves faced with a moral obligation to do what they rightly can to help one of their fellow human beings (a being of moral worth) participate in the true human goods of life and health. In the nontherapeutic situation, the same human beings are still required to recognize in an infant or other incompetent human being the reality that is present to them and demanding of them that it be recognized as the entity that it really is. To authorize that this human being participate in an experiment that is in no way related to his own well-being and in which he is required to participate simply because he can provide an indispensable ingredient for the experiment to work is, I submit, an act that ruptures the convenantal bonds that ought to exist in and among human beings, for it is to regard this human subject, this being of moral worth, either as an impersonal "it" or as a bearer of moral obligations, neither of which he is.

To put it another way, I believe that proxy consent in nontherapeutic situations is morally unjustifiable precisely because it strikes at the very heart of the belief or supposition that lies behind the principle of free and informed consent to begin with, namely that human beings are all, simply by reason of their membership in the human species, beings of moral worth and as such entities that transcend the communities in which they exist.

"Offensive Touching"
A second point that McCormick raised in commenting on the objections raised to his position was the following: "At some point the discussion must come to grips with the fact that Ramsey's position ('offensive touching')—the one preferred by May—could not allow any nontherapeutic experimentation whatsoever, even the
most trivial such as a buccal smear or routine weighing." Let us seek to come to grips with this.

A buccal smear, as I understand it, is tissue taken from human cheeks for examination. I do not know whether such buccal smears are routinely done on infants, but if so, I believe that one ought seriously to question the practice unless it is being done to help or in some way benefit the infants whose cheek tissue is being used for examination. Similarly, if the weighing of infants is in no way related to their well-being, then why is this act performed? Surely any one of us, and I would imagine McCormick would here be included, would be "offended" if someone were to take tissue from our cheeks or put us on a scale simply out of curiosity and without asking our permission. It would be an affront to our dignity, to our humanity. Infants, I submit, and McCormick agrees with me here, are humans in the fullest sense and ought to be respected as such. If a buccal smear or weighing is in no way related to their own well-being, are they not being offensively touched? Does the inoffensiveness reside simply in the minds of those who perform such acts, and is this not the result of their own insensitivity? Does it represent the proper "care" that human beings who are moral agents ought to exercise in behalf of those human beings who are not? Could such activity be made to conform to the Golden Rule as herein articulated?

The suggestion has been made that the position taken by Ramsey and me is too individualistic and does not give serious attention to the social character of our existence. I believe that quite the contrary is true. I agree fully with McCormick when he speaks of the responsibilities that "we" have as members of the human community to do our part to contribute to the general benefit or common good. The obligatory character of these responsibilities is indeed extremely stringent, as a careful consideration of the third mode of obligation of which Grisez speaks would indicate. But I submit that our responsibilities toward the human community include the obligation that "we," that is, moral agents and moral beings, have to protect the integrity and inviolability of those beings of moral worth who are fully our fellow human beings but who are not, precisely because they are children or incompetents, our fellow moral agents charged, with us, with the responsibility to contribute to the general benefit.

REFERENCES
3. AMA Code, art. 1; text in Beecher, p. 221 f.
5. See, for instance, the numerous statements of Pius XII on this matter. Of chief importance are his addresses to the First International Congress on
the Histopathology of the Nervous System (September 14, 1952), to the Sixteenth International Congress of Military Medicine (October 19, 1953), and his Address to the Eighth Congress of the World Medical Association (September 30, 1954). They are conveniently gathered in The Pope Speaks, Vol. 1, nos. 3 and 4 (1954).


9. That membership in the human species is a morally significant fact is repudiated by those, who with Michael Tooley and Joseph Fletcher, distinguish between being a human being and being a person or "enduring subject of experiences, aware of itself as a self." Tooley explicitly denies that membership in the human species is itself morally significant, and this denial is central to Fletcher's thought. See Tooley, Michael, "Abortion and Infanticide," Philosophy and Public Affairs (Fall, 1972), pp. 37-65, and Fletcher, Joseph, "Indicators of Humankind," The Hastings Center Report 2.5 (November, 1972), pp. 1-4.


11. In the broad sense a therapeutic experimentation includes three types of experimental situations: (a) the diagnostic type, in which the purpose is to discover whether a person is suffering from any pathological condition and, if so, what; (b) the strictly therapeutic, in which the purpose is either to cure the pathology or mitigate its effects; and this can be experimentally therapeutic, that is, it may be an experiment that has not been proved effective but is one that offers reasonable grounds for hoping that it will be, even if serious risks are entailed; and (c) the preventive type, in which the purpose is to enable the subject to escape a pathological condition that he does not, at the time, suffer, but to which he is subject as a member of a particular population (e.g., polio vaccines).


13. On this notion of nontherapeutic experimentation see Walters, Le Roy, "Fetal Research and the Ethical Issues," another paper prepared for the Commission and found in Ibid., p. 15.


17. McCormick, Richard A., "Proxy Consent in the Experimental Situation," Perspectives in Biology and Medicine (Fall, 1974). The essay was reprinted with minor changes in Johnston, James and Smith, David, eds., Love and Society: Essays in the Ethics of Paul Ramsey (Missoula, Mont.: Scholars Press, 1974), pp. 209-228 and it is from this latter source that citations are taken here.


20. Ibid. See also his "Notes on Moral Theology," loc. cit., p. 127.

22. The position of McCormick was the one that seemed to provide the basis for the consensus of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. See, for instance, the essays by Peter Steinfels, Le Roy Walters, and Stephen Toulmin in the issue of The Hastings Center Report referred to in notes 12 and 13.


25. Ibid.


28. Grisez, op. cit., pp. 84-86.


31. Ibid., 127.

32. Wertheimer, art. cit., pp. 119-120.


34. This was one of the principal criticisms brought to my attention by readers of the article on experimentation referred to in note 23 in private correspondence.

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