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# Protestant Perspectives on Informed Consent (Particularly in Research Involving Human Participants)

## **Cover Page Footnote**

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# PROTESTANT PERSPECTIVES ON INFORMED CONSENT (PARTICULARLY IN RESEARCH INVOLVING HUMAN PARTICIPANTS)

*James F. Childress\**

## INTRODUCTION

It is virtually impossible to state *the* Protestant position on any bioethical problem or issue. As a result, interpreters must focus on one Protestant position or, at most, identify a few Protestant positions with respect to a particular bioethical problem. Thus, in addressing my assigned topic, I will focus on selected Protestant perspectives on informed consent/refusal, particularly in the context of research involving human subjects or participants.

Several factors contribute to this limitation, not the least of which is that a couple of hundred denominations in the United States march under the banner of Protestantism.<sup>1</sup> Even if we start with the major Reformation traditions, we discover that the Lutheran and Calvinist (Reformed) traditions have splintered,<sup>2</sup> and that the so-called “radical” Reformation, or “left-wing” of the Reformation, encompasses numerous other groups, including the Anabaptists, a label that also covers different denominations.<sup>3</sup>

An attempt to discern a broad Protestant tradition, in contrast to traditions, would necessarily operate at a very high and largely uninformative level of generality. For example, Paul Tillich identified what he called “the Protestant principle,” which represents “the divine and human protest against any absolute claim made for a relative reality, even if this claim is made by a Protestant church.”<sup>4</sup> For Tillich, this principle is “the theological expression of the true relation between the unconditional and the conditioned or, relig-

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1. WORLD CHRISTIAN ENCYCLOPEDIA: A COMPARATIVE STUDY OF CHURCHES AND RELIGION IN THE MODERN WORLD A.D., 1900-2000, at 714-15 (David B. Barrett et al. eds., 1982).

2. JOHN T. McNEILL, THE HISTORY AND CHARACTER OF CALVINISM 4 (Oxford Univ. Press 1967) (1954).

3. *Id.* at 42-25; GEORGE HUNSTON WILLIAMS, THE RADICAL REFORMATION (3d ed., Truman State Univ. Press 2000).

4. PAUL TILlich, THE PROTESTANT ERA 163 (James Luther Adams trans., 1948).

iously speaking, between God and man.”<sup>5</sup> It is “the guardian against the attempts of the finite and conditioned to usurp the place of the unconditional in thinking and acting.”<sup>6</sup> However important this principle is, it provides little guidance about Protestant beliefs and practices, including bioethics.

Yet another limitation is also worth noting. The assigned topic of informed consent, with particular attention to research involving human subjects or participants, has not received extensive treatment in Protestant denominational statements and guidance. To illustrate, I will draw examples from the valuable Park Ridge Center series on different religious traditions’ beliefs and practices regarding health care.

The document on the Lutheran tradition notes that “consistent with their general respect for medicine and informed decision making, [Lutherans] are likely to favor self-determination and informed consent.”<sup>7</sup> The document on the Presbyterian tradition (out of the Calvinist or Reformed tradition) notes that, because of the emphasis on freedom of conscience, Presbyterians would emphasize free exchange of information by patient and caregiver and would tend to err on the side of patient autonomy rather than caregiver paternalism. Turning to research involving human subjects, the document notes that the Presbyterian Church (U.S.A.) “generally supports self-determination and informed consent in medical procedures and experimentation. The General Assembly advocates that ‘human subjects be given the strongest human protections, including full information about the research, and that their consent be obtained without coercion.’”<sup>8</sup>

The Park Ridge Center report on Anabaptist beliefs and practices—including the Mennonites and Amish—notes that no official positions were found on therapeutic or nontherapeutic medical experimentation on various populations or on self-determination and informed consent, but, the report continues, the Anabaptist tradition’s theological-ethical beliefs, such as God’s creation of persons

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5. *Id.*

6. *Id.*

7. THE LUTHERAN TRADITION: RELIGIOUS BELIEFS AND HEALTH CARE DECISIONS 3 (Deborah Harris-Abbott ed., The Park Ridge Ctr. for the Study of Health, Faith, & Ethics 1996).

8. THE PRESBYTERIAN TRADITION: RELIGIOUS BELIEFS AND HEALTH CARE DECISIONS 3 (Deborah Harris-Abbott ed., The Park Ridge Ctr. for the Study of Health, Faith, & Ethics 1996).

in his own image and noncoercion in religious matters, tend to support self-determination and informed consent in such settings.<sup>9</sup>

The report on the United Methodist tradition stresses that, for Methodists, personal autonomy and self-determination are highly valued because God has created human beings in his own image.<sup>10</sup> “The right of persons to accept or reject treatment is protected in a just society by norms and procedures that involve the patient as an active participant in medical decisions . . . .”<sup>11</sup> Informed consent requires disclosure to the patient of all information that a reasonable person would find useful in similar circumstances. This information would include the proposed treatment’s benefits, harms, and risks, as well as alternatives. This report notes that in medical experimentation and research, which are considered important, “it is imperative that governments and the medical profession enforce prevailing medical research requirements, standards, and controls in testing new technologies and drugs on human subjects. The standard requires that those engaged in research shall use human beings as research subjects only after obtaining full, rational, and uncoerced consent.”<sup>12</sup>

These last comments suggest one explanation for the relative dearth of official Protestant statements on and guidance about our topic. There exists an affinity between several Protestant beliefs and practices on the one hand, and requirements of voluntary, informed consent (or refusal) in medicine, health care, and research involving human participants, on the other. Indeed, there is often a convergence or overlap of Protestant religious norms and secular standards of informed consent. This convergence or overlap may result, in part, from historical Protestant influences on social life, including medicine. Sociologists of religion and others have often noted the affinity between major beliefs and practices in Protestantism and individualism,<sup>13</sup> which, when fleshed out, can support voluntary informed consent. As I will stress later, some Protestant beliefs and practices that have supported individualism may have

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9. See *THE ANABAPTIST TRADITION: RELIGIOUS BELIEFS AND HEALTH CARE DECISIONS 2-3* (Ronald P. Hamel ed., The Park Ridge Ctr. for the Study of Health, Faith, & Ethics 1996).

10. *THE UNITED METHODIST TRADITION: RELIGIOUS BELIEFS AND HEALTH CARE DECISIONS 2* (Edwin R. Dubose ed., The Park Ridge Ctr. for the Study of Health, Faith, & Ethics 1995).

11. *Id.*

12. *Id.* at 5.

13. See, e.g., MAX WEBER, *THE PROTESTANT ETHIC AND THE SPIRIT OF CAPITALISM* 105-06, 222 n.22 (Talcott Parsons trans., Charles Scribner’s Sons 1958).

left deposits of norms of conduct that now function independently of their religious origins. Indeed, one interpretation of the process of secularization is that it institutionalizes, in the broader society, values that originated in particular religious traditions—for instance, Talcott Parsons argued that certain Christian values, such as equality, were embedded in the social fabric.<sup>14</sup>

As a result of this historical process, Protestant religious traditions may have little that is materially distinctive to contribute to discussions of voluntary, informed consent. The National Bioethics Advisory Commission (“NBAC”), on which I served from its beginning until its demise from passive euthanasia (non-renewal of its charter) in October 2001, invited scholars of and within particular religious traditions to present testimony on human reproductive cloning and on human embryonic stem cell research. There was great variety on these topics across and within different religious traditions. However, when it prepared its reports on research involving human subjects, NBAC did not specifically invite religious testimony—though, of course, all of NBAC’s meetings were open, and anyone could present testimony during the public comment period, from any standpoint, religious or otherwise, and could submit written testimony any time. Nevertheless, I recall no specifically religious views presented to NBAC while it prepared its report and recommendations on *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity*.<sup>15</sup>

### I. SELECTED PROTESTANT BELIEFS

Which Protestant beliefs lend support to standards of self-determination (autonomy) and voluntary, informed consent/refusal in clinical care and research? Methodologically, Protestants have tended to downplay tradition in favor of direct appeals to scripture, and they have found in, or developed from, scripture several key themes. One major theme from scripture is God’s sovereignty, which Protestants state in a variety of ways.

A second broad theme that Protestants, especially Calvinists, emphasize is that of covenant as represented, for instance, in the

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14. Talcott Parsons, *Christianity and Modern Industrial Society*, in *SECULARIZATION AND THE PROTESTANT PROSPECT* 43, 43 (James F. Childress & David B. Harned eds., 1970).

15. NAT’L BIOETHICS ADVISORY COMM’N, *ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS, VOL. I, REPORT AND RECOMMENDATIONS*, at <http://www.georgetown.edu/research/nrcbl/nbac/capacity/TOC.htm> (Dec. 1998).

sovereign God's covenant with humanity following the flood, with Israel, and in Christ. Sometimes covenant is used as a general category for various relationships with God as creator, provider or orderer, and redeemer, and with other creatures who also image God.<sup>16</sup> One of the most influential Protestant works in modern medical ethics, Paul Ramsey's *The Patient as Person*, which will receive more attention below, presents covenant faithfulness as the primary category for understanding medicine and its responsibilities in light of the Christian faith.<sup>17</sup> Human covenants, such as medicine, can mirror and reflect God's covenants, and such covenants share several features: they are rooted in events or actions; engender moral community; endure over time; and in contrast to contracts, cannot be completely specified.<sup>18</sup> Those covenants, as David Smith notes about Paul Ramsey's thought, follow a "principle of replication . . . as God has committed himself to us, so ought we to commit ourselves to each other. The God-human relationship establishes a standard or norm for person-to-person relationships."<sup>19</sup>

Third, God's covenantal action begins with his creation of human beings in his own *image*, and this conviction has profound implications throughout bioethics. According to the biblical account:

Then God said, 'Let us make man in our image, after our likeness; and let them have dominion . . . .' So God created man in his own image, in the image of God he created him; male and female he created them. And God blessed them, and God said to them, 'Be fruitful and multiply, and fill the earth and subdue it; and have dominion over . . . every living thing that moves upon the earth.'<sup>20</sup>

Interpretations of the image of God usually focus on what is distinctive about persons, particularly their use of reason, exercise of will, making decisions, and the like. Thus, the image of God has been viewed as a theological basis for respect for persons. However, it would be a mistake to construe the image of God as

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16. HESSEL BOUMA III ET AL., *CHRISTIAN FAITH, HEALTH, AND MEDICAL PRACTICE* 83 (1989).

17. PAUL RAMSEY, *THE PATIENT AS PERSON* xiii (1970) [hereinafter *RAMSEY, PATIENT AS PERSON*].

18. See BOUMA ET AL., *supra* note 16, at 85-86.

19. David H. Smith, *On Paul Ramsey: A Covenant-Centered Ethic for Medicine*, in *THEOLOGICAL VOICES IN MEDICAL ETHICS* 7, 8 (Allen Verhey & Stephen E. Lambers eds., 1993).

20. *Genesis* 1:26-28; see also *Genesis* 5:1, 9:6; 1 *Corinthians* 11:7; *James* 3:9.

equivalent to autonomy in the modern liberal tradition. While respect for persons is one way to state the implications of the theological doctrine of the *imago dei*, in mainstream Protestantism, it entails respect for embodied persons—animated body or embodied soul or spirit—not simply their wills, and respect for persons in relation, rather than as atomistic units (even though Protestant beliefs and practices—for example, the stress on individual conscience—have often been taken to support individualism).

Furthermore, the principle of respect for persons, as an implication of the *imago dei*, does not imply unlimited self-determination (autonomy) because autonomy is severely limited by God's creation and will (heteronomy or theonomy). Individuals do not own their bodies or have unlimited dispositional authority over them. Instead, divine ownership and dispositional authority set the context for human trusteeship or stewardship. As Genesis 1:26 indicates, scriptural directions for agents to image or to obey God also include human dominion, which is best understood as trusteeship or stewardship rather than unlimited control.

Fourth, human agents, created in God's image, have both negative and positive obligations. One negative obligation is to refrain from killing themselves or others who are also created in God's image. This obligation is stated not only in the Decalogue ("Thou shalt not kill"), but also in the covenant with Noah after the flood: "Whoever sheds the blood of man, by man shall his blood be shed; for God made man in his own image."<sup>21</sup> Creation in God's image also implies positive obligations. Both the Hebrew Bible/Old Testament and the New Testament stress the positive obligation of neighbor-love, which, in various writings, Ramsey interprets as covenant "faithfulness."<sup>22</sup>

Finally, Protestant convictions about the extent and depth of human sinfulness often play a significant role in recommendations about ways to design and structure institutions, practices, and policies, particularly where some people are especially vulnerable, as in research involving human subjects.

These broad theological convictions often require an ethical bridgework in order to establish explicit connections with practical ethical judgments. For some Protestants, the ethical bridgework can be found in "middle axioms," that is, intermediate moral principles that fall between these broad theological-ethical convictions,

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21. *Genesis* 9:6 (Revised Standard).

22. See *Leviticus* 19:18; *Luke* 10:27-28; see, e.g., PAUL RAMSEY, *NINE MODERN MORALISTS* 235 (1982).



such as the principle of neighbor-love, on the one hand, and particular moral judgments about acts, practices, and policies, on the other hand. Some of these middle axioms focus on ends and consequences of actions, while others focus on the intrinsic or inherent features of actions that tend to make them right or wrong. Examples include a principle of respect for persons (and their autonomous choices) and a rule of voluntary, informed consent/refusal.

## II. PAUL RAMSEY'S PROTESTANT PERSPECTIVE

### A. Ramsey's Theological-Ethical Framework

The late Paul Ramsey was one of the most important Protestant voices in medical ethics, research ethics, and, more generally, bioethics. Given the diversity of Protestantism, he was not and could not be referred to as "representative" of the views of Protestantism as a whole. He waged legendary battles with other Protestants, such as Joseph Fletcher, who over time moved more and more toward a non-religious ethic. Several of these battles focused on bioethics. Ramsey was a Methodist, who was deeply influenced by other Protestant traditions (for example, the Calvinist Karl Barth), by Roman Catholics (he was sometimes called the "Protestant Jesuit"), and by Judaism (he found deep wisdom about embodiment in the Jewish tradition).<sup>23</sup> Ramsey did not develop the theological foundations for ethics as thoroughly as many thought he should have—some even charge that most of the theology in his influential book, *The Patient as Person*, appears in the brief preface, which sketches his covenantal perspective.<sup>24</sup>

In *The Patient as Person* and elsewhere, Ramsey recognized several middle axioms (though he generally eschewed this terminology), particularly in the form of principles or rules that serve as deontological constraints.<sup>25</sup> For reasons that will be clearer later, he attended less to the consequences of actions and practices. Ramsey tended to lump various deontological norms under covenant responsibilities. Writing specifically about the practice of medicine as a covenant, he noted:

*Justice, fairness, righteousness, faithfulness, canons of loyalty, the sanctity of life, hesed, agape or charity are some of the names*

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23. See PAUL RAMSEY, *ETHICS AT THE EDGES OF LIFE: MEDICAL AND LEGAL INTERSECTIONS* xiii-xiv (1970) [hereinafter RAMSEY, *ETHICS AT THE EDGES OF LIFE*]; RAMSEY, *PATIENT AS PERSON*, *supra* note 17, at 154-57, 185-88.

24. See RAMSEY, *PATIENT AS PERSON*, *supra* note 17, at xi-xxii; see also *supra* text accompanying note 17.

25. See RAMSEY, *PATIENT AS PERSON*, *supra* note 17, at xii-xviii.

given to the moral quality of attitude and of action owed to all men by any man who steps into a covenant with another man – by any man who, so far as he is a religious man, explicitly acknowledges that we are a covenant people on a common pilgrimage.<sup>26</sup>

Ramsey does not spell out in detail the connection between the divine covenant and human covenants, but it involves what David Smith calls, as previously noted, a “principle of replication.”<sup>27</sup>

Ramsey’s views reflect a claim about secularization that was noted above: secularization, in part, is the social institutionalization of religious beliefs and practices, with the result that there are historical deposits of religious-ethical norms in the broader society and culture. As a consequence, believers and non-believers alike can appeal to those norms. For instance, Ramsey wrote:

[T]he Judeo-Christian tradition decisively influenced the origin and shape of medical ethics down to our own times. Unless an author absurdly proposes an entirely new ethics, he is bound to use ethical principles derived from our past religious culture. In short, medical ethics nearly to date is a concrete case of Christian “casuistry” – that is, it consists of the outlooks of the predominant Western religion *brought down to cases* and used to determine their resolution.<sup>28</sup>

In an overstatement that makes his point effectively, Stanley Hauerwas interprets Ramsey’s position:

Medicine, at least his account of medicine, confirmed his presumption that agape was in fact instantiated in Western culture. In effect, medicine became Ramsey’s church as doctors in their commitment to patients remained more faithful to the ethic of Jesus than Christians who were constantly tempted to utopian dreams fueled by utilitarian presumptions.<sup>29</sup>

Ramsey’s approach to these historical deposits was largely to interpret, extend, deepen, and refine them, but rarely to reject or fundamentally revise them.

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26. *Id.* at xii-xiii.

27. See Smith, *supra* note 19, at 8; see also *supra* text accompanying note 19.

28. RAMSEY, *ETHICS AT THE EDGES OF LIFE*, *supra* note 23, at xiv.

29. Stanley Hauerwas, *How Christian Ethics Became Medical Ethics: The Case of Paul Ramsey*, in *RELIGION AND MEDICAL ETHICS: LOOKING BACK, LOOKING FORWARD* 70, 79 (Allen Verhey ed., 1996).

### III. NEIGHBOR-LOVE AND JUSTICE IN RESEARCH INVOLVING HUMAN SUBJECTS

In clinical relations, Ramsey recognized the limits of patient autonomy, particularly in the context of decisions about death and dying. The limits he set on patient choices about dying included "medical indications," which dictated clinician's responses.<sup>30</sup> Nevertheless, the requirement of voluntary, informed consent—with greater emphasis on "voluntariness" than on "information"—figures prominently in Ramsey's discussion of research involving human subjects.<sup>31</sup>

In *The Patient as Person*, Paul Ramsey offered an interpretation of research involving human subjects in light of his fundamental theological-ethical convictions, and he further explicated his position in an extended debate with Richard McCormick, S.J., about the use of children in nontherapeutic research.<sup>32</sup> Ramsey's views about the use of children as unconsenting subjects extend *ceteris paribus* to other unconsenting subjects.

The debate between Ramsey and McCormick focuses in part on where to draw the line between charity and justice, and their respective positions depend on several theological, metaphysical, and anthropological convictions (which are closely connected with, but not limited to, Ramsey's Protestant and McCormick's Roman Catholic traditions).<sup>33</sup> Both Ramsey and McCormick appeal to the distinction between love (charity) and justice in order to determine

30. RAMSEY, ETHICS AT THE EDGE OF LIFE, *supra* note 23, at 176-77, 187-88.

31. See RAMSEY, PATIENT AS PERSON, *supra* note 17, at 3-11.

32. *Id.* at 11-19; *infra* note 33 and accompanying text.

33. Ramsey fired the first salvo in *The Patient as Person*. RAMSEY, PATIENT AS PERSON, *supra* note 17, at 11-19. McCormick responded in Richard McCormick, *Proxy Consent in the Experimental Situation*, 18 PERSP. BIOLOGY & MED., Autumn 1974, at 2-20 [hereinafter McCormick, *Proxy Consent*]. This was reprinted in a slightly different version in a Festschrift for Paul Ramsey. LOVE AND SOCIETY: ESSAYS IN THE ETHICS OF PAUL RAMSEY 209-27 (James T. Johnson & David H. Smith eds., 1974). Ramsey responded in Paul Ramsey, *The Enforcement of Morals: Non-therapeutic Research on Children*, 6 HASTINGS CENTER REP., Aug. 1976, at 21-30 [hereinafter Ramsey, *Enforcement of Morals*]. McCormick offered a reply in Richard McCormick, *Experimentation in Children: Sharing in Sociality*, 6 HASTINGS CENTER REP., Dec. 1976, at 41-46 [hereinafter McCormick, *Experimentation in Children*]. Ramsey's further response appeared in Paul Ramsey, *Children as Research Subjects: A Reply*, 7 HASTINGS CENTER REP., Apr. 1977, at 40-42 [hereinafter Ramsey, *Children as Research Subjects*]. For additional themes, see Paul Ramsey, *Some Rejoinders*, 4 J. RELIGIOUS ETHICS 185, 185-237 (1976) [hereinafter Ramsey, *Some Rejoinders*]; see also Richard McCormick, *Experimental Subjects: Who Should They Be?*, 235 J. AM. MED. ASS'N 2197 (1976) [hereinafter McCormick, *Experimental Subjects*]. I have developed my analysis of this debate at greater length in James F. Childress, *Love and Justice in Christian Biomedical Ethics*, in THEOLOGY AND BIOETHICS:

which research, if any, may be performed on human beings without their consent, i.e., without their expressed will or against their expressed will.<sup>34</sup> They agree that acts of charity cannot be demanded or enforced.<sup>35</sup> Such acts can be performed only by individuals who can act voluntarily, and the acts themselves must be voluntary. Ramsey and McCormick also agree that some standards of justice may be enforced even if individuals do not consent to them.<sup>36</sup>

Their different views about which research activities fall under charity and which under justice appear on two levels: (1) the society's pursuit of scientific and medical research, for example, through the allocation of funds; and (2) the individual's responsibility to participate in such research.<sup>37</sup> For Ramsey, scientific and medical research is optional from the society's standpoint, whereas, for McCormick, such research is so important that it is imperative for the society to pursue it.<sup>38</sup> In contrast to McCormick, deontological considerations dominate for Ramsey.<sup>39</sup> By and large, according to Ramsey, the society has moral discretion about pursuing various goals.<sup>40</sup> However, deontological considerations set limits on how it may pursue those goals. Indeed, regarding society's reasons for going to war or for setting its priorities, Ramsey held that moral assessments of goals cannot be as definite or as conclusive as the determination of moral limits on the pursuit of those goals.<sup>41</sup>

Research is often justified as part of humankind's warfare against disease and premature death. However, Ramsey drew a sharp distinction between warfare against disease and premature death, on the one hand, and war against national enemies, on the other.<sup>42</sup> According to Ramsey's distinction, war prevents evil, while research provides positive benefits rather than preventing evils.<sup>43</sup> He often characterizes research as the pursuit of "pro-

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EXPLORING THE FOUNDATIONS AND FRONTIERS 225-43 (Earl E. Shelp ed., 1985), from which I have drawn some ideas and formulations.

34. See *supra* note 33 and accompanying text.

35. See *supra* note 33 and accompanying text.

36. See *supra* note 33 and accompanying text.

37. See *supra* note 33 and accompanying text.

38. Compare Ramsey, *Enforcement of Morals*, *supra* note 33, at 26, with McCormick, *Experimentation in Children*, *supra* note 33, at 43.

39. Ramsey, *Children as Research Subjects*, *supra* note 33, at 40; see Ramsey, *Enforcement of Morals*, *supra* note 33, at 22-24.

40. Ramsey, *Children as Research Subjects*, *supra* note 33, at 41 ("We are to do all the good we morally can, not all the good we can.").

41. RAMSEY, *PATIENT AS PERSON*, *supra* note 17, at 240.

42. See, e.g., Ramsey, *Some Rejoinders*, *supra* note 33, at 185, 229-30.

43. *Id.* at 230.

gress.”<sup>44</sup> From this evaluative description of the research enterprise, Ramsey concludes that research is optional for both societies and individuals.<sup>45</sup>

Ramsey’s sharp distinction between war against disease and premature death and war against national enemies is problematic. In the final analysis, it is probably a distinction between positive and negative goals, rather than positive and negative duties. Surely the duty to prevent evil is a positive rather than a negative duty because it requires positive actions. A common example of a negative duty is the duty of nonmaleficence, that is, the duty not to injure or harm others.<sup>46</sup> However, the duty to prevent such harm or injury involves positive actions; thus, it is more plausibly located under some other principle such as justice or beneficence, rather than nonmaleficence. Nevertheless, within Ramsey’s schema, the duty to refrain from injuring others, and its associated duty to prevent such injury are more stringent than the duty to help others (beneficence).<sup>47</sup> Ramsey also believes that international war can sometimes be construed as preventing evil, but that only research can be construed as producing benefits.<sup>48</sup>

It is not surprising then that Ramsey rejects proposed analogies between conscription for research participation and conscription for military service.<sup>49</sup> But one part of Ramsey’s argument against such analogies does not withstand scrutiny; that is his effort to distinguish conscripted (adult) research subjects from conscripted soldiers. He contends that:

[C]onscripted soldiers are citizens who, though young, have lived in a political society and shared in its safety and other benefits. They have tacitly accepted the benefits of that common good that flow back upon them as individuals, and so also arguably have entered into a community of shared expectations concerning the common defense.<sup>50</sup>

Similar points could plausibly be made about the conscription of adults for participation in nontherapeutic research involving minimal risk, especially if, as Ramsey himself notes, our society tends to

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44. RAMSEY, *PATIENT AS PERSON*, *supra* note 17, at 11.

45. Ramsey, *Children as Research Subjects*, *supra* note 33, at 41.

46. *See, e.g., In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 817 (S.D. Ohio 1995) (stating “individuals in our society are largely left free to pursue their own ends without regard for others save a general duty not to harm others . . . .”)

47. Ramsey, *Children as Research Subjects*, *supra* note 33, at 41.

48. *See* Ramsey, *Some Rejoinders*, *supra* note 33, at 185.

49. *Id.*

50. *Id.* at 230.

view death as always a disaster and tries to avoid it through research, medical care, and the like.<sup>51</sup> "Tacit acceptance" of the benefits of research could, and should, also be construed as entrance into a community of "shared expectations" regarding the war against diseases.

Ramsey's effort to distinguish conscripted (adult) research subjects from conscripted soldiers ultimately depends on his interpretation of legitimate "shared expectations," which in turn depends on his evaluative description of research as optional for society because it promotes benefits, rather than preventing evil. He does grant one "exception" (though he is not sure that it counts as an "exception") that has a "remote analogy" with military service.<sup>52</sup> His example involves children, but extends to others who lack the capacity to consent:

[T]he supposable case must be that *these particular* children are going to be at risk of an illness of calamitous proportions in the near future and if the cure or management of that illness beyond doubt requires their use in medical research. Then they *have* a precisely identifiable share in the common defense against illness, as soldiers do.<sup>53</sup>

However, if this example is plausible in Ramsey's framework, it is not because of the analogy with war, but because this research involving these particular children approximates therapeutic research. The situation is one of "epidemic conditions that bring upon the individual child proportionately the same or likely greater dangers."<sup>54</sup>

The late Hans Jonas, a philosopher, recognized the possibility of conscription for experimentation when the society faced a "clear and present danger," a health emergency, and could avert the disaster only through conscription.<sup>55</sup> This would be a situation of saving, not improving, the society.<sup>56</sup> It is not clear whether Ramsey ever recognized this sort of exception, because he tended to favor

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51. *Id.*

52. *Id.* ("A remote analogy between the citizen-soldier and fetuses and children has, I grant, some point. But only enough to be sufficient reason for a rare exception to a general principle invalidating proxy consent to enter the uncomprehending subjects in nontherapeutic research.")

53. *Id.* (citations omitted).

54. RAMSEY, PATIENT AS PERSON, *supra* note 17, at 25.

55. See generally Hans Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, in EXPERIMENTATION WITH HUMAN SUBJECTS 1, 1-32 (Paul A. Freund ed., 1969).

56. *Id.*

qualifications of the meaning of moral rules rather than explicit exceptions, and because he tended to view medical research almost exclusively in terms of optional improvement for the future, i.e., what Jonas called a “melioristic goal.”<sup>57</sup> At any rate, if a situation such as Jonas depicted came to exist, it could conceivably justify conscription for research of more than minimal risk. However, Ramsey worries that analogies between military conscription and research conscription would in fact allow the society to impose more than minimal risks in research when the goal seems to be of “overriding importance to the public health.”<sup>58</sup> For these reasons, Ramsey appeared to be unwilling to concede an exception of emergency or necessity regarding the public health.<sup>59</sup>

Nevertheless, a society may morally choose to undertake “mankind’s war against diseases.”<sup>60</sup> Holding that “the larger question of medical and social priorities are almost, if not altogether, incorrigible to moral reasoning,”<sup>61</sup> Ramsey allowed the society great latitude in its priorities, for example, research vs. medical care, prevention vs. rescue, or health care vs. other goods. But the society’s *distribution* of its benefits and its burdens is morally constrained. The burdens of research, at least of *nontherapeutic research*, can morally be distributed only to those who voluntarily agree to bear them. *Whether* the society undertakes a war against disease is morally within its discretion, but *how* the society wages that war is not morally optional. It is not permitted to use research subjects against or without their will. This discussion is analogous to Ramsey’s treatment of *jus ad bellum*—the right to wage war—and *jus in bello*—right conduct within war; indeed, the criteria of just research are analogous to the criteria of just war.<sup>62</sup>

Since participation in research cannot be expected or demanded of adults, it cannot be enforced, and it cannot be presumed of an uncomprehending subject. Such “‘construed’ altruism”<sup>63</sup> would be violent even if the risks were low or minimal. Morally, the issue is battery, not negligence. The “altruism” in question concerns the

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57. *Id.* at 14.

58. Ramsey, *Some Rejoinders*, *supra* note 33, at 230.

59. *Id.*

60. Ramsey, *Enforcement of Morals*, *supra* note 33, at 29.

61. RAMSEY, *PATIENT AS PERSON*, *supra* note 17, at 240.

62. See PAUL RAMSEY, *THE JUST WAR: FORCE AND POLITICAL RESPONSIBILITY* 142f (1968); see also JAMES F. CHILDRESS, *PRIORITIES IN BIOMEDICAL ETHICS*, 51-74 (1981); LeRoy Walters, *Some Ethical Issues in Research Involving Human Subjects*, 20 *PERSP. BIOLOGY & MED.* 193, 193-211 (1977).

63. Ramsey, *Some Rejoinders*, *supra* note 33, at 228.

integrity of one's body, rather than risks. Regarding the "burdens of research," McCormick generally denies that low risk or minimal risk research counts as a "burden," while Ramsey views "sacrifice" as "any exaction without one's will," even if it would not be considered supererogatory or heroic if performed voluntarily.<sup>64</sup> The issue is not merely one of charity or altruism in relation to bearing risks, but rather the voluntariness of one's participation.<sup>65</sup>

Furthermore, if altruistic or charitable actions could be construed or constructed for others, there would be no limit, no principle to constrain them, not even the standard of low or minimal risk. Once consequentialist calculation is accepted, it tends to allow the imposition of greater and greater risks. As Ramsey wrote, "I do not see where one could rationally stop in construing all sorts of works of mercy or self-sacrifice on the part of persons, not themselves capable by nature or grace yet of being the subjects of charity."<sup>66</sup>

Because research is optional for the society and for the individual, the researcher and the subject should be voluntary "joint adventurers or partners in the enterprise of medical advancement."<sup>67</sup> This model of joint adventurership or partnership excludes the use of subjects against their will (conscripted of adults), or without their will (the use of uncomprehending persons such as children or persons with mental retardation or psychiatric disorders that affect their decision-making capacity). This model of research participation also coheres with Ramsey's theology of covenantal relations, and a conception of research and participation in research as morally optional.

Ramsey has both negative and positive arguments regarding the importance of voluntary, informed consent (even though "voluntary" and "informed" are used interchangeably in this Essay, it is fair to say, as noted above, that Ramsey emphasized voluntariness rather than disclosure of information).<sup>68</sup> His negative argument reflects his substantive norms, as well as more general Protestant

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64. See McCormick, *Experimentation in Children*, *supra* note 33, at 42.

65. Ramsey, *Children as Research Subjects*, *supra* note 33, at 42 n.8; Ramsey, *Enforcement of Morals*, *supra* note 33, at 30 n.7.

66. Paul Ramsey, *Medical Progress and Canons of Loyalty to Experimental Subjects*, in INST. FOR THEOLOGICAL ENCOUNTER WITH SCI. & TECH., *BIOLOGICAL REVOLUTION—THEOLOGICAL IMPACT* 16 (1973), *quoted in* McCormick, *Proxy Consent*, *supra* note 33.

67. RAMSEY, *PATIENT AS PERSON*, *supra* note 17, at 6.

68. See *id.* at ix, 1-58 (exploring "consent as a canon of loyalty with special reference to children in Medical Investigations.").



convictions about human finitude and, especially, human sinfulness. Ramsey also used a political analogy to make this point about theological anthropology. He quoted and then reformulated Reinhold Niebuhr's famous epigram about democracy: "Man's capacity for justice makes democracy possible; man's propensity to injustice makes democracy necessary."<sup>69</sup> According to Ramsey's reformulation: "Man's capacity to become joint adventurers in a common cause [research] makes the consensual relation possible; man's propensity to overreach his joint adventurer even in a good cause makes consent necessary."<sup>70</sup> The consent of participants in research is necessary in part, then, because researchers as finite and sinful human beings may be tempted to exploit potential and actual participants. Another political analogy also focused on the consent requirement. Ramsey modified Abraham Lincoln's statement, "no man is good enough to govern another without his consent," to read "[n]o man is good enough to experiment upon another without his consent."<sup>71</sup>

One could take this line of argument even farther than Ramsey did in the direction of procedures such as independent review, independent assessment of competence to consent to participation in research, and avoidance of conflicts of interest. Ramsey certainly recognized the dangers of conflicts of interest, for example, in his insistence on the institutional separation of the roles of declaring prospective donors of organs dead and of transplanting donated organs into recipients.<sup>72</sup>

In addition to his negative argument, Ramsey developed a positive argument for the consent requirement in research. Ramsey's positive argument is partly evident in his modification of Niebuhr's quotation: "[m]an's capacity to become joint adventurers in a common cause,"<sup>73</sup> specifically the cause of research. According to Ramsey, as we have seen, research is an optional enterprise for the society and for potential participants.<sup>74</sup> Their participation is a matter of charitable action, not an obligation based on justice. Ideally, the relation in research should be a "joint adventure," "joint

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69. *See id.* at 5.

70. *Id.* at 5-6.

71. *Id.* at 7.

72. *Id.* at 101-12 (referring to the Harvard committee recommendation that "the decision to declare the person dead, and then to turn off the respirator, be made by physicians not involved in any later effort to transplant organs or tissue from the deceased individual.").

73. *Id.* at 5-7.

74. *Id.* at 6.

venture,” “partnership,” “cooperative enterprise,” “voluntary association,” “common enterprise of human medical progress,” and, as noted, a common cause.<sup>75</sup> This basically replicates Ramsey’s covenantal model, theologically construed. Participation in research presupposes voluntary consent; research must be a “consensual relation.”<sup>76</sup>

Ramsey’s language fits well with the recent shift in language utilized to address those involved in research. Earlier, they were called “subjects” in research. While this language could distinguish those persons involved in research from mere “objects,” it also identifies them as individuals who are subjected to research and are, to some extent, under the control of researchers. Now the preferred language in many circles is “participant,” rather than “subject.”<sup>77</sup> Neither term is free of difficulties. “Participant” is terribly broad as it fails to distinguish between the researchers and those actually being studied. And it may represent an ideal that is not met in all circumstances. For example, a child, or other person who lacks sufficient mental capacity, may be enrolled in research, especially therapeutic research, by others. Does the child remain a “subject,” in the historical sense of the designation, or is the child also a “participant,” even though the participation is not voluntary? We have to ask such questions of all metaphors for the relationship between those who conduct research and those who are studied—which metaphors most illuminate the relationship as it exists and as it should exist?

Most of Ramsey’s work appeared at a time when the major focus of ethical analysis was upon nontherapeutic rather than therapeutic research.<sup>78</sup> To some extent, the requirements of justice have been reinterpreted in modern bioethics as a result of a shift in the research paradigm and, consequently, in the perceptions of injustice in research.<sup>79</sup> The earlier paradigm, prominent from the time of

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75. See *supra* notes 67-68 and accompanying text.

76. See *supra* notes 67-68 and accompanying text.

77. See, e.g., NAT’L BIOETHICS ADVISORY COMM’N, *supra* note 15 (referring to recipients of research treatment as ‘participants’ throughout).

78. The terms “nontherapeutic” and “therapeutic” are not fully adequate, but they are used in this article to distinguish research that does not offer a reasonable prospect of medical benefit to the participants (“nontherapeutic”) from research that does offer a chance of medical benefit to the participant (“therapeutic”).

79. See Harold Y. Vanderpool, *Introduction and Overview: Ethics, Historical Case Studies, and the Research Enterprise*, in THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS FACING THE 21ST CENTURY 1, 4-14 (1996) (outlining the developmental history of medical ethics from the time of Nazi experimentation on wartime prisoners through the experiments in Tuskegee, Alabama and into the 1990’s).

Nuremberg, focused on the risks and burdens of research and on the need to protect potential and actual research subjects from harm, abuse, exploitation, and the like.<sup>80</sup> Ethical guidelines for this paradigm emphasize voluntary, informed consent—that is where the Nuremberg Code begins.<sup>81</sup>

According to Carol Levine, our basic approach to regulating research in the United States “was born in scandal and reared in protectionism.”<sup>82</sup> The dominant model in protectionist policies is non-therapeutic research, i.e., research that does not offer the possibility of therapeutic benefit to the subject, and that is the model Ramsey emphasized.<sup>83</sup> In the paradigm shift, however, attention turned from nontherapeutic to therapeutic research (for example, clinical trials of promising new therapeutic agents), from protection to access, and from risks and burdens to possible benefits of research.<sup>84</sup> This shift resulted particularly (but not exclusively) from the epidemic of HIV infection and AIDS.<sup>85</sup>

This inclusionist paradigm is important. However, we should not totally abandon the protectionist paradigm. The hard ethical task is to combine the valuable components of both models in order to protect subjects’ or participants’ rights and welfare in light of a principle of justice—or, for Ramsey, “love-transformed-justice”—that now rejects unjust exclusion as well as exploitation, because vulnerable populations may be threatened by non-inclusion as well as by inclusion.

As a further extension, Ramsey’s model of love and justice in covenantal relations in research provides a strong foundation for compensation for research related-injuries, as an expression of the community’s solidarity with those who suffer injuries in research after assuming a position of risk on behalf of the community. One plausible interpretation of Ramsey’s framework is that such compensation is justified as a matter of justice—love-transformed justice—not merely discretionary beneficence or charity. From this standpoint, it is not enough to disclose on the consent form whether there will be any compensation for research-related inju-

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80. Carol Levine, *Changing Views of Justice after Belmont: AIDS and the Inclusion of ‘Vulnerable’ Subjects*, in *THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS FACING THE 21ST CENTURY*, *supra* note 79, at 105-06.

81. James F. Childress, *Nuremberg’s Legacy: Some Ethical Reflections*, 43 *PERSP. BIOLOGY & MED.* 347, 347-61 (2000).

82. Levine, *supra* note 80, at 105-06.

83. See RAMSEY, *PATIENT AS PERSON*, *supra* note 17, at 12.

84. See Levine, *supra* note 80, at 107.

85. See *id.* at 107-10.

ries that are non-negligently caused; instead, compensation should be provided.

In conclusion, the norms of love and justice reverberate throughout Ramsey's work (and his extended debate with McCormick) on nontherapeutic research involving children who cannot consent (though I have also considered subjects who may be older, but lack the full capacity to consent, as well as those competent persons who refuse to consent). In the context of this debate, McCormick tends to stress the distinction between charity and justice in determining what we can minimally expect and demand of others, even to the extent of exacting it against or without their will.<sup>86</sup> Ramsey also accepts, but tends to downplay that distinction, emphasizing instead what both love (as covenant-faithfulness) and justice (or love-transformed-justice) require of the society, professionals, and family members when they confront potential research participants who lack the capacity to consent or refuse to participate.<sup>87</sup> He emphasizes God's care for the weak and the vulnerable and explicates what this implies for our care for such individuals.<sup>88</sup> Human agape shaped by divine agape requires expression in rules of consent in nontherapeutic research, itself an optional endeavor for both the society and its members. These rules represent historical deposits of neighbor-love, under the influence of the Judeo-Christian tradition.

Finally, although Ramsey's emphasis on consent has affinities with the Kantian tradition of respect for persons, as he admits, his explicit grounds are Christian.<sup>89</sup> Specifically, in relation to the use of children in nontherapeutic research, Ramsey appeals not to the Kantian conception of humanity, but instead to God's agape: "the wholeness of God's care for the least and the littlest ones and their preciousness to Him."<sup>90</sup>

Ramsey's theology and ethics, as extended to requirements of informed consent in research, represent a major and formidable position. Even though it is not without its problems and deficiencies, some of which I have noted in passing, it continues to merit attention and debate as a rigorous interpretation of fundamental Protestant theological beliefs in the context of bioethics. Ramsey insisted that his appeal to Christian beliefs did not finally limit the

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86. See *supra* notes 33-34 and accompanying text.

87. See *supra* notes 33-34 and accompanying text.

88. See *supra* notes 33-34 and accompanying text.

89. See Ramsey, *Enforcement of Morals*, *supra* note 33, at 26.

90. See *id.* at 30 n.19.

audience for his arguments because so many of those beliefs have become embedded in the norms that govern medicine and research. Hence, both believers and non-believers could appreciate and engage his arguments.

