

# *The Need for Ethics Committees, and Their Role and Function*

Nicholas Tonti-Filippini

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Grant me the strength, time, and opportunity always to correct what  
I have acquired, always to extend its domain; for knowledge is  
immense, and the spirit of man can extend indefinitely to enrich  
itself daily with new requirements. Today he can discover his errors  
of yesterday, and tomorrow he can obtain a new light  
on what he thinks himself sure of today.

—MAIMONIDES

This sentiment, contained within the ancient prayer of Maimonides, a physician's prayer, is an expression of commitment to medical research. It is a commitment, fundamental to science as the pursuit of knowledge, to submit one's conclusions to the evidence. In modern science this is known as the hypothetico-deductive (or scientific) method, in which one deduces a hypothesis from a theory and tries to falsify the theory by testing the hypothesis against the gathered evidence.

Maimonides prays that he will always be willing to correct what he believes on the basis of further experience. The modern scientist belongs to a large common enterprise of research in which theories are constantly being tested. Significant results that affirm, falsify, or add to contemporary theories are (or should be) published for the benefit of other researchers and, ultimately, the community. Research and publication are thus most important in the advancement of human knowledge, for upon these enterprises depend the practice and evolution of medicine and the ability to know, understand, and care for the human condition.

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The search for truth on the part of individuals is not the sole end of science. Science serves humanity, not humanity science. Science must never forget that the human being is not a mere means to scientific ends, but the reason for and goal of research:

Basic scientific research, as well as applied research, is a significant expression of man's dominion over creation. Science and technology are precious resources when placed at the service of man and promote his integral development for the benefit of all. By themselves however they cannot disclose the meaning of existence and of human progress. Science and technology are ordered to man, from whom they take their origin and development; hence they find in the person and in his moral values both evidence of their purpose and awareness of their limits.<sup>1</sup>

Honesty in one's work and in the publication of results, and a commitment to ensuring that humanity is the goal and not merely the means of such work, are crucial to the integrity of medical science and medical scientists.

The prayer of Maimonides is above all an expression of humility, a willingness to serve rather than dominate humanity: "The eternal providence has appointed me to watch over the life and health of Thy creatures. May the love for my art actuate me at all times; may neither avarice nor miserliness, nor thirst for glory or for a great reputation engage my mind; for the enemies of truth and philanthropy could easily deceive me and make me forgetful of my lofty aim of doing good to Thy children. May I never see in the patient anything but a fellow creature in pain."

The central function of bioethics committees is to guide the development of medical science so that it genuinely seeks knowledge within the context of recognizing that each human being is created in God's own image and likeness. Each has inherent human dignity and equal and inalienable rights.

### **The Need for Ethics Committees**

Historically, ethics committees developed from peer review. The necessity for them became apparent in the first half of the last century when there were many instances of medical research that put the interests of research ahead of the importance of the research subject.

The Oath of Hippocrates was a part of Western medicine until the early twentieth century, when it ceased to be regarded as a commitment required of the medical profession. That period involved great developments in medical science and research. However, it also saw the development within medicine of a keen interest in genetics and the emergence of a strong eugenics movement. That era spawned some great evils, such as the compulsory sterilization of children and adults classified as mentally subnormal, and harmful experiments on them and on members of racial groups thought to be inferior.

We often point to the atrocities, in this respect, of the Nazi regime, made particularly horrific with the extension of such discriminatory activity to include "non-Aryan" groups such as Jews, in addition to other groups such as homosexu-

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<sup>1</sup>*Catechism of the Catholic Church* (New York: Doubleday, 1994), n. 2293. See also Congregation for the Doctrine of the Faith, *Donum vitae* (February 22, 1987), Introduction, 2.

als. But it should be born in mind that the Nazi doctors were not the only doctors to lose awareness of the inherent human dignity and equal and inalienable rights of all members of the human family.

In America, the effects of disease during the First World War led to significant numbers of people being used as research subjects between the wars and during the Second World War:

The effects of this association between the war and medical research ... were to further undermine any concern for the welfare of research subjects. It was considered valid to put research subjects at considerable risk in experiments that had no possible therapeutic advantage to them. The needs of the war effort predominated. Research subjects drawn from mental asylums and state penitentiaries were infected with malaria and given experimental antidotes to test the therapeutic effectiveness of the antidote, the relapse rate and the severity of side effects.<sup>2</sup>

The Tuskegee Study was an infamous research project involving poor black men from rural areas in the southern United States in whom the progress of untreated syphilis was observed. The study began in 1932 and continued until the mid 1960s, even though treatments for syphilis, especially antibiotics, were developed in the 1940s and had become readily available. The Willowbrook State School case involved mentally disabled children who were deliberately infected with hepatitis. Only children whose parents agreed to their participation in the study gained admission to the school.<sup>3</sup>

California's eugenics law permitted the forcible sterilization of over twenty thousand mentally disabled men and women between 1909 and 1970. Similar provisions existed in other states and in the United Kingdom, where the Mental Deficiency Act of 1913 provided for the compulsory sterilization of those in mental asylums. There are also published reports of both prisoners and the inmates of asylums being given X-ray therapy as an experimental treatment for head lice.

The worst abuses of that tragic era in Western medicine came to light, however, in the trials of the Nazi doctors after the Second World War. Responding to those abuses, Pius XII set out, in an address to the First International Congress of Histopathology (1952), the principle that a human subject cannot be used as a mere means to gain medical knowledge for the common good:

Can the public authority, whose function it is to care for the common good, give the doctor the power to make experiments on the individual in the interests of science and the community, in order to invent and try out new methods and processes when these experiments infringe on the right of the individual to dispose of himself? ...

The great postwar trials have brought to light a frightful quantity of documents testifying to the sacrifice of the individual to "medical interests of the community." In these acts are found testimonies and reports which show how, with the assent,

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<sup>2</sup>Paul M. McNeill, *The Ethics and Politics of Human Experimentation* (Cambridge, U.K.: Cambridge University Press, 1993).

<sup>3</sup>Ruth R. Faden, Tom L. Beauchamp, and Nancy M. P. King, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986).

and sometimes even by formal command of the public authority, certain centers demanded a regular supply of men from concentration camps for their medical experiments. We learn how men were delivered up to the centers; so many men, so many women, so many for this experiment, so many for that. ...

Insofar as, in the cases mentioned, the moral justification of the intervention is based on the mandate of the public authority, and therefore from the subordination of the individual to the community, of the individual good to the social good, it rests on a mistaken application of the principle. It must be pointed out that man, as a person, in the final reckoning, does not exist for the use of society; on the contrary, the community exists for man.<sup>4</sup>

The principles established to prosecute the Nazi doctors became known as the Nuremberg Code.<sup>5</sup> A major principle in the Nuremberg Code was that human research subjects had to have the legal capacity to consent and had to be adequately informed. Thus, children and the mentally disabled were excluded. Ensuring that research subjects were not exploited was the responsibility of all those involved in the research. Other conditions for research on human subjects included necessity, prior animal experimentation, minimization of harm, effects not disabling, proportionate risk, protection of subject, qualified persons to carry out the research, subject at liberty to end the experiment, and experiment ended if shown to be injurious.

The Nuremberg Code was strict in its provisions as a reaction of indignation to the atrocities committed in medical research during the Second World War and the period preceding it. The main aspect of that strictness was emphasis placed on the consent of the subject and the exclusion of those who are too young, or mentally disabled and unable to consent.

In 1964, after many years of deliberation, the World Medical Association released its own statement of principles, the Declaration of Helsinki.<sup>6</sup> A major new feature was the allowance of proxy, or represented consent, for those who were unable to consent themselves. This addition was heavily qualified: the research could be carried out on these subjects only if it could not be carried out on normal adults; the research had to have as its purpose benefit to the population group that the subjects represented; and the condition of the subjects that made it impossible to obtain their consent had to be the condition that identified the group as needing the research.

The declaration also identified the issues surrounding therapeutic and nontherapeutic research. In particular, the declaration adopted stringent standards in relation to combining research with medical care (see section C, clauses 28–33) and potential conflicts of interest between the goals of research and the goals of medical care.

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<sup>4</sup>Pius XII, *Allocution to the First International Congress of Histopathology* (September 13, 1952), in *The Human Body: Papal Teachings*, selected and arranged by the Monks of Solesmes (Boston: Daughters of St. Paul, 1960), 202–204.

<sup>5</sup>See “The Nuremberg Code” in *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, vol. 2 (Washington D.C.: U.S. Government Printing Office, 1949), 181–182, <http://history.nih.gov/laws/pdf/nuremberg.pdf>.

<sup>6</sup>See World Medical Association, “Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects” (June 1964), <http://www.wma.net/e/policy/b3.htm>.

A difference between the Declaration of Helsinki and the Nuremberg Code is that at Helsinki an effort was made to reclaim the integrity of the medical profession. Nuremberg made consent of the subject the priority. Helsinki retained this, but allowed some research on those unable to consent, while emphasizing the need for medical integrity in research goals and design and in treatment of human subjects.

There are significant gaps in the Declaration of Helsinki, notably the vexed question of conflicts of interests in view of the receipt of research funds from companies that have a commercial interest in the outcome of the research. Direct or indirect, explicit or implied restraints on publishing unfavorable data or conclusions are not addressed.

Also significant is the failure to address who qualifies as a human subject. This is especially of concern now that somatic cell fusion with an ovum (cloning) and the dismembering of human embryos to obtain stem cells has become a major issue. There are also moves to extend the definition of death so that those who are not brain dead but are in a permanent state of unresponsiveness (sometimes misleadingly called a “vegetative” state) may be treated as though they were dead and used experimentally or as a source of tissue. The declaration also fails to deal with the question of the handling and ownership of tissue taken from human bodies.

Finally, the declaration is silent about the issues involved in the commercialization of medical research and the many issues arising from the human genome project and genetic research, including (1) manipulation of the human genome; (2) ownership or patenting of genomic information and gene sequences; (3) human–animal transgenesis in the formation of human–animal hybrids; (4) privacy issues, including family and group privacy issues; (5) reproductive uses of stored or removed human tissue; (6) ethical issues in the use of human DNA or gene sequences, including reproductive uses; (7) the selling of the genome of whole populations to commercial interests; (8) the use of genetic information or of tissue in ways not envisaged by the donors; and (9) and the problem of developing diagnostic or prognostic genetic information that in the absence of treatment or cure greatly increases the scope for unjust discrimination, especially reproductive discrimination.

Having begun as a form of peer review, ethics committees gradually became broader in their composition as it became apparent that they needed to be more independent. However, many are still appointed by the institutions they serve, even though they are likely to include some persons who are not from those institutions. They have an important role in providing independent review of medical research proposals, and in some institutions they also have a role in reviewing clinical practice. On the negative side, they can develop a life of their own, privileged by their role, independent of the community, not accountable to the community, secretive and identified with the interests of the institution they serve.

The researchers themselves may dominate an ethics committee. This is often because the nonmedical members rely on their information and advice. But by training and expertise the researchers are committed to research aims, and those aims may not reflect the interests of the research subjects or the interests of the wider community.<sup>7</sup> The Declaration of Helsinki states that an ethical review committee “must be independent of the investigator, the sponsor or any other kind of undue influence.”

## Consent to Medical Research and Disclosure

### *Informed Consent*

To intervene medically, the health care professional should have the express or tacit consent of the patient.<sup>8</sup> Pope Pius XII expressed this very clearly in 1957: “The doctor, in fact, has no separate or independent right where the patient is concerned. In general he can take action only if the patient explicitly or implicitly, directly or indirectly, gives him permission.”<sup>9</sup>

Without such authorization, the doctor gives himself an arbitrary power. “The patient cannot be the object of decisions which he will not make, or, if he is not able to do so, which he could not approve. The ‘person,’ principally responsible for his own life, should be the center of any assisting intervention: others are there to help him, not to replace him.”<sup>10</sup> Pope John Paul II described the patient as “the responsible person, who should be called upon to share in the improvement of his health and in becoming cured. He should be given the opportunity of personally choosing, and not be made to submit to the decisions and choices of others.”<sup>11</sup>

The process of obtaining permission, or consent, is often complex, as there are several elements that are considered important, such as whether the patient possesses all the information that would be likely to affect his decision to consent to intervention, whether the patient is free from any form of coercion that would affect the decision, and whether the patient comprehends the information and is able to relate the decision to the information. Thus, the issue turns on whether the patient is informed, free, and competent in relation to the decision to consent.

In North America, the notion of *informed consent* is used: a consenting person who lacks relevant information may be considered to have not consented at all. In some other jurisdictions, the notion of informed consent is separated into two distinct notions: the duty of disclosure, which is an aspect of the duty of reasonable care (failure to comply may be considered to be professional negligence); and the matter of trespass to the person if a procedure is carried out without consent. John Paul II asserts that the patient should be given a precise idea of his illness and the

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<sup>7</sup>McNeill, *Ethics and Politics of Human Experimentation*, 6.

<sup>8</sup>Pontifical Council for Pastoral Care to Health Care Workers, *The Charter for Health Care Workers*, (1995), n. 72.

<sup>9</sup>Pius XII, Address to an International Congress of Anesthesiologists (November 24, 1957), n. 1, in *L'Osservatore Romano*, November 25–26, 1957; available at [http://www.lifeissues.net/writers/doc/doc\\_31resuscitation.html](http://www.lifeissues.net/writers/doc/doc_31resuscitation.html).

<sup>10</sup>Pontifical Council *Cor Unum*, “Some Ethical Questions Relating to the Gravely Ill and the Dying” (July 27, 1981), in *Enchiridion Vaticanum 7, Documenti ufficiali della Santa Sede 1980–1981* (Bologna, Italy: Edizioni Dehoniane Bologna, 1985), 1137, n. 2.1.2.

<sup>11</sup>John Paul II, Address to the World Congress of Catholic Doctors (October 3, 1982), in *Insegnamenti di Giovanni Paolo II*, vol. V/3 (Vatican City: Libreria Editrice Vaticana, 1982), 673, n. 4.

therapeutic possibilities, with the risks, the problems, and the consequences that they entail, so that he can make a choice with full awareness and freedom.<sup>12</sup>

### *Duty of Disclosure*

Telling the truth is, in the first instance, a matter of respect for knowledge. Developing in understanding is a major part of human flourishing, which can bring us closer to God as we understand ourselves better and thus know more about God, in whose image and likeness we were made. Informing a competent patient of the truth in relation to diagnosis and prognosis is not only a matter of respecting the patient's own capacity to make decisions for himself; it is a matter of assisting that person in his own path toward God. Withholding information or, worse, deceiving a patient is not only coercive; it frustrates the patient's personal development by creating misunderstanding.

In medical research, it is particularly important that patients are adequately informed. This is the function of having statements in plain language and ensuring that lay people can fully understand them. More than that, it is incumbent on the research team to ensure that research subjects do actually understand what is involved at each step of the way.

Informing patients, especially very ill patients, is a gradual process. The way the doctor gives information should help a patient understand the illness, management options, and reasons for any intervention. It may sometimes be helpful to convey information in more than one session. The doctor should (1) communicate information and opinions in a form the patient understands; (2) allow the patient sufficient time to make a decision—the patient should be encouraged to reflect on opinions, ask more questions, consult with the family, a friend, or an advisor, and be assisted in seeking another medical opinion when this is requested; (3) repeat key information to help the patient understand and remember it; (4) give written information or use diagrams, where appropriate, in addition to talking to the patient; (5) pay careful attention to the patient's responses to help identify what has or has not been understood; and (6) use a competent interpreter when the patient is not fluent in the doctor's language.<sup>13</sup>

### *Proxy Consent to Therapeutic or Nontherapeutic Research*

At the end of life and at other times when a patient's ability to understand and make his own decisions may be compromised by disability or illness, difficult decisions must sometimes be made about medical intervention. Such difficulty may be greatly exacerbated when the proposal is for therapeutic or nontherapeutic research rather than for general treatment.

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<sup>12</sup> John Paul II, "A Patient Is a Person," Address to Two Congresses of Physicians and Surgeons (October 27, 1980), in *The Pope Speaks* 26.1 (1981): 1–5.

<sup>13</sup> Australian National Health and Medical Research Council (NHMRC), "Guidelines on Informing Patients" (Canberra, Australia: NHMRC, 1993).

It is worth noting that the statement of commitment for medical researchers proposed by the Pontifical Academy for Life does not envisage that those unable to consent will be subjects of research: “I will treat each person who submits to an experiment as a free and responsible subject and never as a mere means to achieve other ends. I will never let a person be involved in an experiment unless he/she has given his/her free and informed consent.”<sup>14</sup>

The Nuremberg Code is similar:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision.<sup>15</sup>

But the Declaration of Helsinki allows for proxy consent for incompetent research subjects: “For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law.”<sup>16</sup>

A strong reason for allowing research on young children, the mentally ill or mentally disabled, and those who through senility or illness are not competent is that advances in medicine for people in those categories would otherwise be very limited, and they would be denied the benefits of advances in their care which could be achieved through research. Totally excluding such people, as a group, from research would not be in their best interests.

It is important to note, however, that this argument justifies research on incompetent people only if it is in their direct interest, or at least in the interest of the group to which they belong. On those grounds the Declaration of Helsinki limits such research to what is necessary for the relevant group of persons. The use of people who cannot consent for research for the benefit of other groups in the community is thus excluded. The problem still remains of how to justify research which is not in the direct interest of the non-competent person and which carries some risk of harm.<sup>17</sup>

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<sup>14</sup>Pontifical Academy for Life, “Proposal of an Ethical Commitment for Researchers in the Biomedical Field,” appendix to “Concluding Communiqué on the ‘Ethics of Biomedical Research: For a Christian Vision’” (February 26, 2003), [http://www.vatican.va/roman\\_curia/pontifical\\_academies/acdlife/documents/rc\\_pont-acd\\_life\\_doc\\_20030226\\_ix-gen-assembly-final\\_en.html](http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pont-acd_life_doc_20030226_ix-gen-assembly-final_en.html).

<sup>15</sup>Nuremberg Code, n. 1.

<sup>16</sup>Declaration of Helsinki, n. 24.

<sup>17</sup>U.S. law provides various protections for individuals who have limited competence to give informed consent. These are found in 45 CFR 46, “Protection of Human Subjects,” subparts B (Pregnant Women, Human Fetuses, and Neonates), C (Prisoners), and D (Children). With few exceptions, children cannot be subject to more than minimal risk unless there is a direct prospect of benefit.

Therapeutic research poses a complex range of problems in the mixing of research and therapy motives. There is a particular need to disclose the research interest so that the person making a consent decision in the interests of a subject can take the research interest into account as well, and to ensure that the integrity of the decision to treat is not compromised by research or commercial interests. The making of decisions to treat on behalf of another person is a complex responsibility.

These matters were analyzed in great detail by Pope Pius XII. In relation to the doctor's rights and duties, Pius XII taught, "The rights and duties of the doctor are correlative to those of the patient."<sup>18</sup> He addressed the question of the representation of an incompetent patient in the following way:

What we have already said is true also of the legal representative of anyone incapable of disposing of himself and of his affairs: for example, children who have not arrived at the age of reason, the feeble of mind, the insane. Such legal representatives, appointed by a private decision or by public authority, do not possess over the body and the life of their subordinates any other rights than they themselves would have, if they were capable of it, and to the same extent. They cannot then give the doctor permission to dispose of them outside of these limits.<sup>19</sup>

In this legal representative, Pius XII appears to be envisaging both what we would now call a *donee of an enduring power of attorney*, appointed by the patient while competent, and what we would call a *guardian or deputy* appointed by the state. In relation to medical treatment, Pius XII teaches that the representatives of the patient have the same rights over the body and life of the patient that the patient, if competent, would have. However, the notion of rights that Pius XII used was a notion that limited the exercise of individual rights within the scope of moral responsibility. The subjective decision about treatment would be qualified by traditional moral responsibilities toward one's own health and life and the health and life of others. With regard to proxy consent, it is consent to medical treatment, as opposed to nontherapeutic research, that seems to be approved by Pius XII.

In recent times, most Western jurisdictions have attempted to qualify the powers of a patient's representative in relation to medical intervention, inserting *patient's best interest* clauses and reference to the *patient's previously expressed wishes*. The inclusion of such clauses gives the health professional and other concerned persons the opportunity to question the adequacy of the representation and seek to have the representation reviewed. Where the representative seems to be acting—inadvertently or otherwise—contrary to the patient's interests, then I would argue that health professionals have an obligation to seek that review.

A problem that can occur is tension between a *best interest* notion based on the welfare of the proposed research subject and the *patient's previously expressed wishes*, where the patient had previously expressed a desire to be involved in research but the research endangers or compromises his welfare. There is much discomfort

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<sup>18</sup>Pius XII, Address to International Congress of Anesthesiologists, n. 1.

<sup>19</sup>Pius XII, Allocution to First International Congress of Histopathology, 201.

over a representative affirming the earlier decision when the individual is no longer able to make such an altruistic choice. Altruism cannot be exercised *on behalf of* someone else. What is altruism on my part may become exploitation when someone else makes the decision for me.

Some jurisdictions in Australia simply exclude all research on incompetent subjects which is not in their interests or would significantly endanger their physical, emotional, and psychological safety.<sup>20</sup>

### **Professional Integrity and Patient Autonomy**

An emergent issue is the extent to which doctors who uphold traditional values in relation to human life and dignity may find themselves confronted by circumstances in which their employing institutions, colleagues, or patients request the doctor's cooperation in activities that are not consistent with the doctor's own values.

A gap is emerging in the "culture of death" between traditional norms of medical practice and research and the new notion that a patient's autonomous choice validates a procedure that would otherwise have been considered unethical. The patient's informed choice within the consent process has several facets, reflecting different ethical standards: permission, authorization or validation, and demand. In the first instance, a doctor offers reasonable care according to traditional ethical standards of the profession but requires the patient's *permission* before proceeding.

In the second instance, *reasonable care* applies only to the competent delivery of a service, and the consent of the patient gives ethical authority or validation, *and that is all that is needed* to meet ethical standards: there is no recognition of an objective ethical standard. Often, the defense of doctors offering new reproductive technologies or dubious procedures such as sexual reassignment surgery has been simply that the patient consented. The patient's consent is understood to put aside or override other moral qualms or professional ethical requirements.

In the third instance, the choice of the patient *entitles the patient to expect* the service from the doctor, whatever the doctor's ethical reservations. This is increasingly the case in relation to postcoital intervention, for instance, experiments in reproductive technology to treat infertility or to produce children for relationships not involving a man and a woman, and experiments in the area of sexual "reassignment."

There are objective moral limits on free choice.

In this discussion it is important to recognize the confrontation between a traditional Hippocratic ethic and liberal bioethics. This is a confrontation with a new moralism, a moralism that asserts autonomy as the supreme value. On analysis, one can identify three main liberal propositions:

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<sup>20</sup>See, for example, NHMRC, *National Statement on Ethical Conduct in Research Involving Humans* (Canberra, Australia: NHMRC, 1999), <http://www.nhmrc.gov.au/publications/synopses/e35syn.htm>.

- Autonomy provides the basis of human dignity: You possess dignity by virtue of your present autonomy, your future autonomy (infants), or your past autonomy (senile elderly). Human beings who never possess autonomy lack human dignity, although there still may be morally weighty reasons for protecting and caring for them. Autonomy is thus the basic moral category. This position has two variants: one accords equal dignity to everyone who possesses or has possessed a threshold level of dignity; the other says the greater the level of autonomy of an individual, the greater the human dignity.
- Autonomy is the sole intrinsic good by which the quality of life (as distinct from the extent to which we esteem persons, and as distinct from the intrinsic value of the person's life) is to be assessed. Everything else, such as health and education, is seen as relevant in its effect on autonomy.
- Considerations of the autonomy of those directly involved in an individual case always morally override all other considerations in deciding what ought to be done.

The philosopher Gerald Dworkin comments:

There is an intellectual error that threatens to arise whenever autonomy has been defended as crucial or fundamental: This is that the notion is elevated to a higher status than it deserves. Autonomy *is* important, but so is the capacity for sympathetic identification with others, or the capacity to reason prudentially, or the virtue of integrity. Similarly, although it is important to respect the autonomy of others, it is also important to respect their welfare, or their liberty, or their rationality. Theories that base everything on any single aspect of human personality, on any one of a number of values, always tend toward the intellectually imperialistic. One way in which this is done is by assimilating other concepts to that of autonomy.<sup>21</sup>

In defense of authority (such as medical authority) Dworkin writes:

We lack time, knowledge, training, skill. In addition there is necessary and useful division of labor. It is more efficient for each of us to specialize in a few areas of competence and be able to draw, when we need it, upon the resources and expertise of others. Knowledge is socially stored, and there are evolutionary advantages for a species that does not require each individual member to acquire and retain the knowledge needed for survival and reproduction. It may also be true that our reliance upon authority assumes that somewhere in the chain of authority ... someone has engaged in (weak or strong) checking.<sup>22</sup>

A crucial matter in this debate is the notion of professional integrity and the ideal of joining a profession in order to develop and apply one's knowledge and skills in a way that serves the needs of another. Being a health professional means being committed to goals such as caring for those who are sick and preventing ill health. Those are objective goals, and they dignify the profession.

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<sup>21</sup>Gerald Dworkin, *The Theory and Practice of Autonomy* (Cambridge: Cambridge University Press, 1988), 32.

<sup>22</sup>*Ibid.*, 45–46.

Most theories based on autonomy do not give validity to choice, regardless of what is chosen. Many autonomy idealists appeal to various notions of *rational* autonomy. But the more sophisticated such theories become, the further removed they are from mere choice, and the more they import notions of reasoned choice that apply standards other than choice. In other words, a kind of natural law develops that imposes objectively rational criteria.

One issue that is confounding for autonomy idealists is the fact that people can make autonomous choices that harm autonomy, such as committing suicide or taking drugs.<sup>23</sup> If autonomy were a moral trump, then to protect autonomy, one would be required to prevent voluntary suicide that ends an autonomous life and prevent the abuse of drugs that diminish rational function or that are addictive. One must distinguish between respecting a *person* because he *is autonomous* (has the ontological status of being a chooser)—or, more particularly, is rationally autonomous (a rational chooser)—and respecting a person's *choices* in relation to self-regarding matters as to what is morally right for him—autonomy as a *moral trump*.

The first is the position taken by Aristotle and Aquinas in relation to man as a rational animal who possesses free will. Because a man is the kind of being he is, he warrants respect for his worth and dignity. Precisely because we value him, we are not prepared to harm him, even if he wishes it.

Within the Catholic tradition, we recognize that there are both objective and subjective elements in the making of a decision about medical treatment or participation in medical research which involves risks. In the latter case, the subject's personal sensitivities will affect the decision to be altruistic; however, there are objective limits to the nature of the harm that he may be permitted to accept. Significant risks to life or to the functional integrity of his body or mind are not acceptable.

Pope John Paul II, in a 1980 address to two congresses of physicians and surgeons, clarified the way in which an individual may legitimately contribute to the common good through medical experimentation:

Except in special cases, the essential purpose of the patient in cooperating with the experiment is the improvement of his or her health. Any such experiment

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<sup>23</sup> Immanuel Kant is often cited as the father of autonomy idealism. But Kant opposed suicide because it destroyed an autonomous individual, and in his own painful terminal illness he would forego pain relief in order to maintain lucidity. "Firstly, under the head of necessary duty to oneself: He who contemplates suicide should ask himself whether his action can be consistent with the idea of humanity as an end in itself. If he destroys himself in order to escape from painful circumstances, he uses a person merely as a mean to maintain a tolerable condition up to the end of life. But a man is not a thing, that is to say, something which can be used merely as means, but must in all his actions be always considered as an end in himself. I cannot, therefore, dispose in any way of a man in my own person so as to mutilate him, to damage or kill him. (It belongs to ethics proper to define this principle more precisely, so as to avoid all misunderstanding, e.g., as to the amputation of the limbs in order to preserve myself, as to exposing my life to danger with a view to preserve it, etc. This question is therefore omitted here.)" Immanuel Kant *Fundamental Principles of the Metaphysics of Morals*, trans. Thomas Kingsmill Abbott (London: Longman, 1959, repr. 1965).

derives its primary justification from the way it serves the interests of the individual, not of the collective.

This does not mean, however, that, provided his or her own substantial integrity is preserved, the patient may not legitimately accept a share of risk as a way of making a personal contribution to the progress of medicine and thus to the common good. Medical science exists in the community as a force that is meant to liberate human beings from the infirmities which encumber them and from the psychic and somatic weaknesses that lay them low. Such a gift of oneself, within the limits set by the moral law, can, therefore, be a highly meritorious proof of love and an occasion for spiritual growth of such magnitude as to offset the dangers of a possible physical diminution that is not substantial in kind.<sup>24</sup>

On the limits of what the patient could consent to, Pius XII taught:

As far as the patient is concerned, he is not absolute master of himself, of his body, or of his soul. He cannot, therefore, freely dispose of himself as he pleases. Even the motive for which he acts is not by itself either sufficient or determining. The patient is bound by the immanent purposes fixed by nature. He possesses the right to use, limited by natural finality, the faculties and powers of his human nature. Because he is the beneficiary, and not the proprietor, he does not possess unlimited power to allow acts of destruction or of mutilation of anatomic or functional character. ...

The patient has not the right to involve his physical and psychic integrity in medical experiments or researches, when these interventions entail, either immediately or subsequently, acts of destruction, or of mutilation and wounds, or grave dangers.

Furthermore, in exercising his right to dispose of himself, of his faculties and organs, the individual must observe the hierarchy of the scale of values,—and within an identical order of values, the hierarchy of individual goods, to the extent demanded by the laws of morality. So, for example, man cannot perform upon himself or allow medical operations, either physical or somatic, which beyond doubt do remove serious defects or physical or psychic weaknesses, but which entail at the same time permanent destruction of, or a considerable and lasting lessening of freedom, that is to say, of the human personality in its particular and characteristic function.<sup>25</sup>

Often researchers are inclined to use themselves as research subjects. It is important to note that they are not morally free to endanger their own lives or the functional integrity of their own bodies and minds.

In his 1954 address to the Congress of the World Medical Association, Pius XII addressed this matter:

What pertains to the doctor with regard to his patient is equally applicable to the doctor with regard to himself. He is subject to the same broad moral and juridical principles as govern other men. He has no right, consequently, to permit scientific or practical experiments which entail serious injury or which threaten to impair his health to be performed on his person; and to an even lesser extent

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<sup>24</sup> John Paul II, “A Patient is a Person,” 4.

<sup>25</sup> Pius XII, Allocution to First International Congress of Histopathology, 198–199.

is he authorized to attempt an operation of experimental nature which, according to authoritative opinion, could conceivably result in mutilation or suicide. This also applies, moreover, to male and female nurses, and to anyone who feels himself disposed to offer his person as a subject for therapeutic research. He cannot expose himself to such experimentation.<sup>26</sup>

### Research at the Beginning of Life

New technologies involving the use of embryonic and fetal tissue in research and the formation of embryos other than by fusion of sperm and ovum give rise to new questions about who or what is a human subject of research, worthy of protection from being treated as mere tissue rather than as a fully human subject. A crucial question now is, What constitutes an embryo?

#### *Conception and the New Technology*

In 1987, the Congregation for the Doctrine of the Faith wrote:

From the moment of conception, the life of every human being is to be respected in an absolute way because man is the only creature on earth that God has ‘wished for himself’ and the spiritual soul of each man is ‘immediately created’ by God; his whole being bears the image of the Creator. Human life is sacred because from its beginning it involves ‘the creative action of God’ and it remains forever in relationship with the Creator, who is its sole end. God alone is Lord of life from its beginning until its end: no one can, in any circumstances, claim for himself the right to destroy directly an innocent human being.<sup>27</sup>

“Conception” once had a clear meaning: a woman conceived a child when, through union with her husband, sperm and ovum fused to form one cell and that one-cell embryo began its development within her toward human adulthood. But artificial reproduction and cloning technologies produce human embryos separately from a woman’s “conceiving,” in the sense of becoming pregnant. Embryo transfer by which a woman comes to be *with child* is a separate event. In that separation, the child’s natural inheritance of a strong and unambiguous relationship to parents through an origin in their union becomes attenuated, and parenthood becomes separable into distinct roles: genetic, gestational, technological, and social. An embryo may be conceived in a laboratory without directly involving genetic parents. The embryo may be conceived without a woman having conceived it.

Made available in the laboratory, and sometimes abandoned there, human embryos are in danger of being treated as a mere source of experimental tissue.<sup>28</sup> We have seen the recent development of technologies by which human embryos

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<sup>26</sup>Pius XII, Allocution to the Eighth Congress of the World Medical Association (September 30, 1964), in *The Human Body: Papal Teachings*, selected and arranged by the Monks of Solesmes (Boston: Daughters of St. Paul, 1960), 315.

<sup>27</sup>Congregation for the Doctrine of the Faith, *Donum vitae*, Introduction, 5.

<sup>28</sup>Scientists who do not themselves destroy human embryos but are prepared to use cell lines derived from recently destroyed human embryos are closely complicit in the destruction of the embryos concerned.

may be manufactured by processes other than the fusion of a sperm and an ovum, as in cloning, for example, where a human somatic cell is fused with an enucleated human or animal ovum.

The definition of the embryo based on the formation of a new cell from the fusion of sperm and ovum (for example, in *Donum vitae*) does not apply to an embryo formed by other means. This warrants careful thought about a new definition that encompasses the new possibilities.

### *Role of the Genome*

Scientifically, we are able to distinguish a human being from other living beings at the moment the first cell is formed. We can so distinguish it because a human zygote has a human genome. In the natural order, its genome determines that it is a human being and not an animal. Only in connection with this genome does God create a new, ensouled human being. In the union of a man and a woman, we have the perfect way in which that act of divine creation is preceded by the couple's "responsible collaboration with the fruitful love of God."<sup>29</sup> But the biological effect of the union of a man and a woman in creating a new life is the formation of a new human genome, to which each has contributed equally, and it appears as a matter of evidence that it is partly through that genome that the offspring is created as a human being, a being made in the image and likeness of God, inheriting that human status.

The new organism with the human genome directs the cell reproduction process in such a way that growth does not happen in an amorphous or undirected way, but a complex structure forms which, given a favorable environment and nourishment, will normally exhibit those characteristics that we acknowledge to be particularly human: the capacity for love, wonder, and reason and for forming a relationship with God.

When a scientist creates, or attempts to create, an embryo by mixing human and animal material—for example, by fusing a human somatic cell with an enucleated animal ovum—he confuses the identity of what is or is not human, who is or is not made in the image and likeness of God, and who does or does not count as my neighbor. In doing so, and in producing an embryo by a manufacturing process, the scientist fails to respect the sacredness of human procreation and the part the human genome plays in procreation.<sup>30</sup>

### **Research Involving Other Vulnerable Groups**

There are other categories of research subjects who are vulnerable because they have a dependent relationship which may induce them to participate in research against their best interests or inclinations. The question of inducements to participate in research arises not only when there is direct payment for participation, but

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<sup>29</sup>Vatican Council II, *Gaudium et spes* (December 7, 1965), n. 5.

<sup>30</sup>Nicholas Tonti-Filippini et al., "Ethics and Human-Animal Transgenesis," *National Catholic Bioethics Quarterly* 6.4 (Winter 2006): 689-704.

also when there is fear that service may otherwise be denied, or when participation provides access to services that would not otherwise be available. An inducement to participate in a procedure that one would otherwise reject is problematic, in that it undermines one's dignity, integrity, and respect for oneself, one's mind and body. It puts a price on the worth of oneself, one's health and life, by making them subject to being traded. An inducement to participate in research also compromises one's freedom to choose, especially if one is poor or has otherwise been denied needed services. It is no accident that analysis of the background and social status of research subjects shows a disproportionate number being less educated and less wealthy. When an inducement is offered, there is also a danger that the researcher may not feel so obliged to protect the subject from risks or discomfort. The researcher may feel that he has less of a duty to care, because the research subject is not a true volunteer and owes something in return for the payment. The researcher may feel that the research subject who is paid should earn his payment.

*Prisoners.* Prisoners are particularly vulnerable for several reasons:

- There may be an attitude that they owe something to society or that they are somehow less deserving than others of ordinary protection and concern.
- Their circumstances are usually highly restricted and inhumane by ordinary standards, and participation in research may relieve them of boredom or prison duties, allow them respite from the prison regimen and from other prisoners, or provide contact with the research team ("normal people"), which would otherwise be a very restricted privilege.
- For security reasons prisoners are subject to the management decisions of others in all matters, and their participation in research may be not an entirely free choice but rather more of a directive.
- Provision of health services in prisons is not always optimal, and research participation may be seen as a way of obtaining better medical care.

*Students.* Students who are asked to be research subjects by a supervisor, lecturer, or someone with assessment responsibilities are in a relatively powerless position and may feel pressured to "volunteer."

*Employees.* Similarly, employees seeking promotion or other betterment or simply trying to hold onto their jobs may feel pressured to accept the suggestion that they participate in research. Employers with research interests may in fact feel that the employees owe their employer some sort of loyalty, should share in the employer's interests, and hence should consent to research.

*Military Personnel.* The military are seen as having given themselves to the service of their country, surrendering ordinary freedoms in order to form a security force where they put themselves in danger for the sake of the community. It then seems a small step to have them become research participants for the sake of the community. They can, in fact, be ordered to do so and, if their rights are not well defined, they may feel obliged to obey such an order. Their freedom to consent or refuse is thus compromised, and this is a matter that needs to be taken into account in deciding to accept their consent to participate.

*Children.* We have already looked at research on human embryos (children at the very start of their lives). Children are not, at any stage, the property of their parents. It is important to ensure that parental consent is in the child's interests. Where a child is more mature, then the child's consent may be more important, or both parental consent and the child's consent may be required. It is important to note that a child is usually influenced by his parents and may comply because he feels that compliance is what the parents want.

*People with Developmental Disabilities.* People with developmental disabilities may need to be represented. They may be more than usually open to suggestion, they are often dependent on others, and they may tend to trust the authorities in their lives. There is a tragic history of people with developmental disabilities being exploited as research subjects in projects that would not have been carried out on more able persons. The reasons for this appear to be discriminatory.

*People with Mental Illness.* People with mental illness are vulnerable in similar ways to those who are developmentally disabled. They may also be vulnerable to new and relatively untried treatments because so much mental illness is intractable. In the relationships they have with psychiatric staff, they are often reliant on the judgments of others, because their illness affects their capacity to make decisions. They are also sometimes certified and forced to undergo treatment without their consent. Therapeutic research in such circumstances is highly problematic. There is a particular need for careful review to ensure that research is in these subjects' interests.

*Other Patients.* Patients of all kinds are vulnerable to research suggestions made in the context of a therapeutic relationship on which they depend. They may feel that they will be denied treatment or be classified as difficult patients if they do not consent to suggestions that they participate in research.

## **Bioinformatic Research**

Bioinformatics is the application of mathematics, information technology, and statistics to the extensive data generated by modern genetics and biomedicine. It may involve (1) research and development of tools and techniques for molecular sequence analysis and estimation of differences between different genomes using such techniques as phylogenetic tree construction; (2) research and development of methods for the analysis of gene expression data; (3) research and development for the analysis of protein expression data (proteomics); (4) research and development in data mining techniques to link genetic data with phenotypic data in populations or in drug-discovery data libraries; (5) advice and assistance in molecular sequence analysis and phylogenetics; (6) courses and training in biological computing and analysis; (7) establishment of genetic and medical databases for whole populations and for population groups; and (8) application of all these techniques to practical problems of both local and international significance, such as virology, epidemiology, genomics, proteomics, pharmacology, biopharmacology, health resource allocation and planning, community health education, and population policy development.

Bioinformatics is a new and rapidly evolving discipline. Highly specialized skills have already developed, and continue to develop, but they have not really

begun to be fully exploited. The power to analyze huge amounts of data rapidly and to answer complex questions in a very short time (questions that would previously have taken years of painstaking and very tedious research) has already had dramatic effects on research and development in pharmacology, biopharmacology, diagnostic and prognostic technology, and the understanding of disease processes for the purposes of both prevention and treatment.

The old notions of identified and de-identified information and tissue have had to be revised in the face of the reality that much information can be mined from genetic data or human tissue; and this, combined with the matching of databases by computerized analysis using mathematical techniques for linking and correlating data, mean that it is often possible to re-identify information that is particular to an individual.

There are major question about who owns information and whether ownership of genetic information is an appropriate concept. Custodianship and regulated use seem preferable to notions of ownership. We have already seen entrepreneurs being permitted to buy the genetic information of whole populations for research purposes.

There is much at stake. The understanding of disease and the development of new therapies, particularly pharmaceutical or biopharmaceutical therapies, is being revolutionized. For instance, new therapies are being computer-designed to combat viruses based on modeling of the molecular structures of the viruses and their interaction with human cells. Molecular biology is now a central discipline underpinning virtually all fields of medical research.

The downside of greater knowledge about disease and about propensities for disease is the greater scope for discrimination, which may take many forms, including reproductive discrimination and loss of freedom and opportunity. Many of the issues involve the collection of data or tissue and the presumptions involved in permitting data collection; how the data may be used, including end-uses by third parties; security and confidentiality; and maintenance of the information quality. The significance of the new capacities in terms of benefits and implications for studied populations is only just beginning to be realized.

### **The Operation of Ethics Committees**

Common mistakes made in the appointment of ethics committees compromise their independence and capacity; they include the appointment of (1) lawyers who are associated with the law firm that represents the interests of the institution rather than lawyers who have in mind the interests of research subjects; (2) clinical and research professionals from within the institution who are likely, directly or indirectly, to be associated with the research projects of the institution; (3) lay people and others selected by and known to the administrators of the institution, rather than members nominated by the wider community and selected for their expertise, experience, and independence; (4) clerics or other representatives of religion who have not studied the pertinent specialized areas of medical or research ethics; (5) no persons who represent the interests of those who are vulnerable to research, such as children, the aged, and those who are chronically ill, developmentally disabled, physically disabled, or mentally ill; (6) no person with a formal training in medical or research ethics.

*Conflicts of Interest*

Conflicts of interest are often interpreted very narrowly to include pecuniary interests only. The Declaration of Helsinki refers to such affiliations. There is, however, a need to take into account direct and non-direct pecuniary and non-pecuniary interests of members of ethics committees and their families, bearing in mind career, corporate, and financial connections that may be particularly affected by decisions on matters that come before the committee. Committees need to have methods of dealing with conflicts of interest. Normally the process should be a committee member's disclosure and voluntary exclusion from discussions of the item representing the conflict, unless the committee itself sees reason to bring the member back into the discussion. Many committees simply have disclosure and not exclusion.

*Accountability*

Research ethics committees often deal with matters containing elements that, if disclosed, would compromise the commercial viability of a project by informing competitors. Those interests often need to be protected simply for the sake of obtaining funding for research through the development of findings to a point that they have a commercial value. However, commercial interests should not outweigh the interest that the community has in being informed about the nature of research. Ethics committees ought to be prepared to have their decisions, and the reasons for them, subjected to community scrutiny. Otherwise there is a danger of a small, informed, and elite group developing a culture that is separate from the wider community, and which sees no need to explain itself to the community. In such circumstances ethics committees may become tools for social validation rather than genuine review.

Ethics committees should publish their proceedings. Matters of great commercial value might be edited out and published only when the need for withholding information from competitors has passed. It should never be the case that information is withheld from the community because the information might be disturbing to the community or cause a community reaction. If that happens, then the committee has indeed isolated itself from the community to whom it should be accountable.

*Ethics Committee Procedures*

With the workload involved, ethics committees can see themselves as permission-granting bodies, a hurdle for researchers to jump along the way to gaining funding or publication. Ethics committees should in fact be instructive for researchers, seeking always to improve the ethics of research. The chairperson of an ethics committee responsibly ensures that researchers are aware of the discussion that took place; that members have an opportunity to express their opinions; and that reporting reflects the range of views of the members, including the opportunity for each to dissent and to have, on request, the rationale for the dissent recorded and included in reports.

*Ethical Leadership*

Ethics committees present a particular challenge of trying to integrate often very differing points of view. They tend to work on the basis of seeking consensus, but often that means that a majority may overrule minorities. Often there are very few members who are trained in an ethical discipline such as moral theology or

moral philosophy. Several different disciplines may be represented, and there may be problems of language and culture.

In a secular context, there can be resistance to what is seen as moralizing. For my own purposes, I have identified several common moral-discussion stoppers. They are (1) an appeal to moral pluralism, the assumption that people disagree on moral questions; (2) a claim that one should not judge others; (3) a claim that morality is a private matter; and (4) a claim that morality is culturally determined. The challenge is to respond in ways that help them see that morality is an intellectual activity that has a method and rigor like any other.

The task for a Catholic member of a secular ethics committee is not to seek to impose a view, but to seek to illuminate human goodness in such a way that it is recognized by reason—even by the reason of the unfaithful—and willingly chosen.

### **Bioethics Committees in Catholic Institutions**

Bioethics committees in Catholic institutions have a different function. Their role is to articulate a Christian response to new problems. There may be discomfort about articulating that mission. It is important to have a clear idea of what the dynamic is. An obvious first question is, What is theology?

I have tried to answer this by saying that theology means (1) thought and talk about God—theology is about ourselves (and everything else) considered in relation to God; (2) reflection upon the sources in which the truth of faith is articulated; (3) natural theology and theodicy—philosophical theology—applying the light of reason; (4) sacred theology—applying the light of faith; (5) systematic theology, seeking to determine the relationship between the truths of faith and other propositions which are not revealed.<sup>31</sup>

Christian ethics, then, is a branch of theology that studies human acts so as to direct them to a loving vision of God seen as our true, complete happiness and our final end. This vision is attained by means of grace, the virtues, and the gifts of the Holy Spirit, in the light of revelation and reason.<sup>32</sup> Often people approach ethics in a religious institution with an authoritarian idea that we simply need to apply commandments written in stone. But the reality is that Christian morality is a dynamic, guided by revelation but needing to understand the concrete circumstances and to seek truth within the shifting reality of the human condition. Above all, Christian morality respects the voluntariness of our choices. We are free and not determined. Our ethics are not just about the morality of individual acts, but about the individual, his vocation. We are conscious of the interior as well as exterior dimensions of acts. Our morality is teleological—right moral choices are aimed toward our ultimate end—happiness in communion with God

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<sup>31</sup> Germain Grisez, *The Way of the Lord Jesus*, vol. 1, *Christian Moral Principles* (Quincy, IL: Franciscan Herald Press, 1983), 3ff.

<sup>32</sup> Servais Pinckaers, O.P., *The Sources of Christian Ethics*, 3rd ed. (Washington, D.C.: Catholic University of America Press, 1995).

In Christian teleology we seek communion with God and to develop in God's image and likeness. We are made in the image of God and with freedom to choose whether to be like God. Beatitude connotes the fullness of happiness. The Beatitudes were not a command but an instruction in what would make us happy—blessed. We recognize a final end or supreme goal toward which our whole life and all our actions are directed. It is important that an ethics committee acknowledges that human beings are called to be happy.

An ethics committee in a Catholic institution thus needs to address the relationship between faith and reason. John Paul II expressed it beautifully in *Fides et ratio*: “Faith and reason are like two wings on which the human spirit rises to the contemplation of truth; and God has placed in the human heart a desire to know the truth—in a word, to know himself—so that, by knowing and loving God, men and women may also come to the fullness of truth about themselves.”<sup>33</sup>

In *The Sources of Christian Ethics*, Servais Pinckaers poses the question, What is Christian ethics? A science based exclusively on rational norms with revelation simply confirming and providing external inspiration? Or based principally and sourced from revelation?

For John Paul II, faith and reason are like the wings of an eagle—both are necessary. For Pinckaers, reason is the power of human intelligence simultaneously open to spiritual enlightenment (faith) and faithful to rigorous discipline of thought (reason). Pinckaers poses the further question, Is morality about moral obligation? He answers, Morality is the science of happiness, not the science of obligation.

- Obligation cannot create friendship, but friendship can create obligations.
- Giving is the path to happiness, not because we are rewarded for giving, but because being a giver is intrinsic to our happiness.
- The central point of Christian morality is to act in a way that expresses our orientation toward God, because it is in acting in accord with our natures (*imago Dei*) that we are happy.
- Obligation, then, is an expression of our vocation to be happy.

For Aquinas, our purpose or end as human beings is twofold, the goal or end that we seek, and the attainment or enjoyment of that goal. Our ultimate end is God, who alone can perfectly satisfy man's will. Happiness is our attainment of enjoyment of that end, and that happiness we thus create in ourselves. Within the Catholic tradition, an ethics committee takes human dignity as a core notion. Dignity is intrinsic or inherent. It belongs to a human being simply by his being a member of the human family and thus made in the image and likeness of God, and it means that no member of the human family may be used, or treated merely as an object of use.

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<sup>33</sup> John Paul II, *Fides et ratio* (September 14, 1998), opening statement.