Bioethics Committees

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1. Introduction

> "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."

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 method in which one deduces an 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 those enterprises depends the practice and

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evolution of medicine and the ability to know, understand and care for the human condition.

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 and goal for 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."[1]

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 in relation to serving rather than dominating 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 recognising that each human being

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[1] Congregation for the Doctrine of the Faith, *Donum Vitae,* 1987, Section 2 (Also quoted in the Catechism of the Catholic Church, 1993, n. 2293).

is created in God's own image and likeness. Each has inherent human dignity and equal and inalienable rights. My in this presentation is to offer a brief guide to those engaged in bioethics committees that reflects the importance of their activity.

2. 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 of a keen interest in genetics and the coming to be of a strong eugenics movement within medicine. That era spawned some great evils such as the compulsory sterilisation of children and adults classified as mentally sub-normal, 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 homosexuals. 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."[2]

The *Tuskegee Study* was an infamous research project involving poor black men from rural areas in the south of the United States in whom the progress of untreated syphilis was observed. The study began in 1932 and continued until the mid-1960s, even though there were treatments readily available, especially antibiotics, which emerged during the 1940s.

The *Willowbrook State School* case involved mentally disabled children who were deliberately infected with hepatitis. Only those whose parents agreed to them participating in the study gained admission to the school.[3]

California's eugenics law permitted the forcible sterilization of over 20,000 mentally disabled men and women between 1909 and 1970. Similar provisions existed in other States and in the United Kingdom where the Mental Health Act 1930 provided for the compulsory sterilisation of those in mental asylums. There were 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 (1956),[4] the principle that a human subject cannot be used as a mere means to gain medical knowledge for the common good:

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[2] Paul McNeill, *The Ethics and Politics of Human Experimentation* (Cambridge University Press, 1993).

[3] R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent* (Oxford University Press, 1986).

[4] Pius XII, "The Intangibility of the Human Person," Allocution to the First International Congress of Histopathology, September 13, 1952, in *The Human Body: Papal Teachings* (Daughters of St. Paul, 1960), p. 207.

> "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?...
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> "The great post-war 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, and sometimes even by formal command of the public authority, certain centres demanded a regular supply of men from concentration camps for their medical experiments. We learn how men were delivered up to the centres; 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."

The principles established to prosecute the Nazi doctors became known as the *Nuremberg Code.*

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
- Risk proportionate
- Protection of subject
- Qualified persons to carry out

- Subject at liberty to end the experiment
- 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 upon 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 deliberation, the World Medical Association released its own Declaration of Helsinki. 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 with respect to:

- The research not being able to be carried out on normal adults;
- For the purposes of benefit to the population category that the person represents;
- The condition preventing the obtaining of consent is the characteristic that identifies that group as needing the research.

The Declaration also identified the issues surrounding therapeutic and non-therapeutic research. In particular, the Declaration adopted stringent standards in relation to combining research with medical care (see *Declaration* section C, clauses 28-33) and the conflict of interest that may exist between the goals of research and the goals of medical care.

A difference between the Declaration of Helsinki and the Nuremberg Code is that at Helsinki there was an effort 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 unfavourable 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 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.

There is also a failure 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 commercialisation of medical research and the myriad issues arising from the human genome project and genetic research, including

- manipulation of the human genome;
- ownership or patenting of genomic information and gene sequences;
- human-animal transgenesis in the formation of human-animal hybrids;
- privacy issues including family and group privacy issues;
- reproductive uses of stored or removed human tissue, human DNA or gene sequences;
- the selling of the genome of whole populations to commercial interests;
- the use of genetic information or of tissue in ways not envisaged by the donors;
- 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 that they serve, even though they are likely to contain some persons who are not from within the 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 non-medical members rely upon 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 research subjects or the interests of the wider community.[5]

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".

2. Consent to Medical Research and Disclosure

2.1 What is informed consent?

To intervene medically, the health care professional should have the express or tacit consent of the patient.[6] Pope Pius XII expressed this very clearly in 1957:

> "[The doctor] "does not have a separate and independent right in relation to the patient. In general, he can act only if the patient explicitly or implicitly (directly or indirectly) authorizes him."[7]

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[5] Paul McNeill, *The Ethics and Politics of Human Experimentation*. Cambridge University Press, 1993, p. 6.

[6] Pontifical Council for Pastoral Care to Health Care Workers, *Charter for Health Care Workers*, 1995, n.72.

[7] Pius XII, To the doctors of the G. Mendel Institute, Nov. 24, 1957, in AAS 49 (1957) p. 1031.

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 centre of any assisting intervention: others are there to help him, not to replace him".[8]

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."[9]

The process of obtaining permission, or informed consent, as it is usually termed, 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 or her decision to consent to intervention;
- Is free from any form of coercion that would affect the decision; and
- 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 not to have 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);

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[8] Pont. 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 (EDB, 1985), p. 1137, n. 2.1.2.

[9] John Paul II, To the World Congress of Catholic Doctors, Oct. 3, 1982, in 'Insegnamenti' V/3, p. 673, n. 4.

- 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 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.[10]

2.2 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 him or herself; it is a matter of assisting that person in his or her own path towards God. Withholding information, or worse, deceiving the 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 upon 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 the reasons for any intervention. It may sometimes be helpful to convey information in more than one session. The doctor should:

- Communicate information and opinions in a form the patient should be able to understand;

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[10] John Paul II, To the participants at two congresses on medicine and surgery, Oct. 27, 1980, in 'Insegnamenti' III/2, 1008-1009, n. 5.

- 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 advisor, and be assisted in seeking other medical opinion where this is requested;
- Repeat key information to help the patient understand and remember it;
- Give written information or use diagrams, where appropriate, in addition to talking to the patient;
- Pay careful attention to the patient's responses to help identify what has or has not been understood;
- Use a competent interpreter when the patient is not fluent in the language being used.[11]

2.3 Proxy consent to therapeutic or non-therapeutic research

At the end of life and at other times when a patient's ability to understand and make his or her own decisions may be compromised by disability or illness, there are sometimes difficult decisions to be made about medical intervention. The difficulty may be greatly exacerbated when the proposal is for therapeutic or non-therapeutic research.

It is worth noting that the proposed *Statement of Commitment* for medical researchers developed by the Pontifical Academy for Life (see section three) 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."

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[11] National Health and Medical Research Council, *Guidelines on Informing Patients* (Australian Government Printer, 1993).

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."

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."

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 whom they belong. On those grounds the *Declaration of Helsinki* limits such research to that which 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.

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 persons making decisions can take them into account in making a decision in the

interests of the represented person, and to ensure that the integrity of the decision to treat is not compromised by research and/or commercial interests.

The making of decisions to treat on behalf of another is a complex responsibility.

These matters were analysed in great detail by Pope Pius XII. In relation to the doctor's right and duties, Pius XII taught:

> "The rights and duties of the doctor are correlative to those of the patient. 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."[12]

Pius XII addressed the question of the representation of an incompetent patient in the following way:

> "What We say here must be extended to the legal representation of the person incapable of caring for himself and his affairs: children below the age of reason, the feeble-minded and the insane. These legal representatives authorized by private decision or by public authority, have no other rights over the body and life of those they represent than those people would have themselves if they were capable. And they have those rights to the same extent. They cannot, therefore, give the doctor permission to dispose of them outside of those limits."[13]

In this statement, 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 as the patient him or herself would have had. However,

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[12] Pius XII, Address to a Symposium of the International Congress of Anaesthesiology, n. 24, 1957 AAS 49, p. 103.

[13] Pius XII, Address to 1st International Congress on Histopathology of the Nervous System 14/9/52.

the notion of rights that Pius XII used was a notion that limited the exercise of individual rights within the scope of moral responsibility (see section 4.4 below). The subjective decision about treatment would be qualified by the traditional moral responsibilities towards 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 non-therapeutic 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 to 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 has previously expressed a desire to be involved in research and the research endangers or compromises his or her welfare. There is much discomfort 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 simply exclude all research on incompetent subjects which is not in their interests and/or would significantly endanger their physical, emotional and psychological safety.[14]

[14] See for instance the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (**NHMRC,** 2000) at http://www.nhmrc.gov.au/publications/synopses/e35syn.htm.

3. Does professional integrity override 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 employing institutions, colleagues or patients request the co-operation of the doctor 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 newfound notion that the patient's autonomous choice validates a procedure that might otherwise have been considered unethical. The patient's informed choice within the consent process has several facets:

- Permission,
- Authorization or validation, or
- Demand.

In the first instance, consent means what it means when a doctor offers what would be regarded by the profession as reasonable care within the ethical standards of the profession, but requires the patient's *permission* before proceeding.

In the second instance, the *reasonable care* applies only to the competent delivery of the 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 defence 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 any 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 professional whatever the latter's ethical reservations. This is becoming increasingly the case in relation to post-coital intervention, for instance, and there are other instances such as experiments in reproductive technology to treat infertility or to produce children for relationships not involving a man and a woman, and experimentation in the area of "sexual re-assignment".

There are objective moral limits on free choice.

In this discussion it is important to recognize what the confrontation is 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:

a) Autonomy provides the basis of human dignity: you possess dignity in virtue of your present autonomy, your future autonomy (infants), or your past autonomy (senile elderly), and human beings who never possess autonomy lack human dignity, though there still may be morally weighty reasons for protecting and caring for them. In these ways autonomy is 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.

b) 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 via its effect on autonomy.

c) Considerations of the autonomy of those directly involved in the 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."[15]

In defence 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 specialise 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."[16]

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.

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 mere 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,

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[15] Gerald Dworkin, *The Theory and Practice of Autonomy* (Cambridge University Press, 1988), p. 32.

[16] Ibid., 45-6.

such as suicide[17] or drug-taking. If autonomy were a moral trump, then in order to protect autonomy, one would be required to prevent voluntary suicide that ends an autonomous life or prevent the abuse of drugs that diminish rational function or which are addictive.

One must distinguish between respecting a *person* because he or she *is autonomous* (has the ontological status of being a chooser), or more particularly 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 or her – autonomy as a *moral trump.*

The first is the position taken by Aristotle and Aquinas in relation to man the 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 recognise that there are both objective and subjective elements in the making of a decision about medical treatment or to participate 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 which he or she may be permitted to accept. Significant risks to life or to the functional integrity of his or her body or mind are not acceptable.

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[17] 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 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's *Fundamental Principles of the Metaphysics of Morals,* translated by Thomas Kingsmill Abbott, 1965.

Pope John Paul II, in an address to two congresses of physicians and surgeons (1980), 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 derives it primary justification from the way it serves the interests of the individual, not of the collective.
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> "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."[18]

On the limits of what the patient could consent to, Pope 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...
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> "The patient has not the right to involve his physical and psychic integrity in medical experiments or researches, when these

[18] John Paul II, "A Patient is a Person," Address to Two Congresses of Physicians and Surgeons, Oct. 27, 1980, in *The Pope Speaks* 26/1 (Spring 1981), 1-5 at 4.

> interventions entail, either immediately or subsequently, acts of destruction, or of mutilation and wounds, or grave dangers.
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> "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..."[19]

Often, researchers are inclined to use themselves as research subjects. It is important to note that they are not morally free to endanger life or their own functional integrity of body and mind.

In an address to the Congress of the World Medical Association (1954), 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 own person; and to an even lesser extent 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."[20]

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[19] Pius XII, "The Intangibility of the Human Person," Allocution to the First International Congress of Histopathology, Sept. 13, 1952, in *The Human Body: Papal Teachings* (Daughters of St. Paul, 1960), p. 207.

[20] Pius XII, "Moral Problems in Medicine," Allocution to the Eighth Congress of the World Medical Association, Sept. 30, 1964, in *The Human Body: Papal Teachings* (Daughters of St. Paul, 1960), p. 315.

4. Research at the Beginning of Life

1.1 New technologies, new questions

New technologies involving the use of embryonic and foetal 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 and 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?*

4.2 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."[21]

"Conception" once had a clear meaning: a woman conceived a child when, through her 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 'conceiving', in the sense of becoming pregnant. Embryo transfer by which a woman becomes *with child* is a separate event. In that separation, the natural inheritance of a strong and unambiguous relationship to parents through an origin in their union becomes attenuated – parenthood becomes separable into distinct roles: genetic, gestational, technological and social. An embryo may be conceived in the laboratory without directly involving the genetic parents. The embryo may be conceived without a woman having conceived.

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[21] *Donum Vitae* I 5.

Made available in the laboratory, and sometimes abandoned there, human embryos are in danger of being treated as a mere source of experimental tissue.[22] Further, we have seen the recent development of technologies by which human embryos may be manufactured other than by the fusion of a sperm and an ovum; for example, cloning, where a human somatic cell is fused with an enucleated human or animal ovum.

The definition of the embryo based upon formation of a new cell from the fusion of sperm and ovum (see *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.

4.3 Role of genome

Scientifically we are able to distinguish a human being from other living beings at the moment that the first cell is formed. We can so distinguish it because a human zygote has a human genome. In the natural order, it is its genome that 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".[23] 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 have 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 favourable environment and nourishment, will

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[22] 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.

[23] *Gaudium et Spes,* n. 5.

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 or she confuses the identity of what is or is not human and what or who is or is not made in the image and likeness of God, and does or does not count as my neighbour. In so doing, 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.[24]

6. Other Vulnerable Groups

There are other categories of research subject who are vulnerable because they have a dependant relationship which may induce them to participate in research when they would not otherwise have chosen to be involved.

The question of inducements to participate in research arises not only where there is direct payment for participation, but also where there is fear that there may be denial of service otherwise or where participation provides access to services that would not otherwise be available.

An inducement to participate in a procedure that the person would otherwise reject is problematic in that it undermines 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 freedom to choose, especially if the person is poor or otherwise denied needed services. It is no accident that analysis of the background and social status of research subjects shows a disproportionate number coming from the less educated and less wealthy, as individuals or as communities.

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[24] Nicholas Tonti-Filippini, John I. Fleming, Gregory K. Pike, Ray Campbell, "Ethics and Human-animal Transgenesis", forthcoming in *Medicina e Morale,* 2003.

There is also a danger that where an inducement is offered, the researcher may not feel so obliged to protect the subject from risks or discomfort. The researcher may feel that he or she has less of a duty of care because the research subject is not a true volunteer and owes some return for the payment. The researcher may feel that the research subject who is paid should earn his or her payment.

a) 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 regime and 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 the offer to participate in research may not be entirely free but may be more of a directive.
- Provision of health services in prisons is not always optimum and research participation may be seen as a way of obtaining better medical care.

b) 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".

c) 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 some sort of loyalty to their employer or share in interests of the company that provides employment and hence should consent to research.

d) Military

The military are seen as having given themselves to the service of their country, surrending 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. In fact they can 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.

e) 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.

In this it is important to note that a child is usually influenced by his or her parents and may comply because he or she feels that it is what the parent wants.

f) People with developmental disability

People with developmental disability may need to be represented. They may be more than usually open to suggestion and they are often dependant on others and simply trust the authorities in their lives.

There is a tragic history of people with developmental disability 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.

g) People with mental illness

People with mental illness are vulnerable in a similar way to those who are developmentally disabled.

They are also 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 upon the judgements 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 the research is in the subject's interests.

h) Other patients

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

7. Bioinformatic Research

7.1 Introduction

Bioinformatics is the application of mathematics, information technology and statistics to the large-scale data generated by modern genetics and bio-medicine. This may involve:

a) Research and development of tools and techniques for molecular sequence analysis and estimation of differences between different genomes using techniques such as phylogenetic tree construction;

b) Research and development of methods for the analysis of gene expression data;

c) Research and development for the analysis of protein expression data (proteomics);

d) Research and development in data mining techniques to link genetic data with phenotype data, in populations or in drug discovery data libraries;

e) Advice and assistance in molecular sequence analysis and phylogenetics;

f) Courses and training in biological computing and analysis;

g) Establishment of genetic and medical databases for whole populations and for population groupings; and

h) Application of the above to assist practical problems of both local and international significance such as virology, epidemiology, genomics, proteonomics, pharmacology, bio-pharmacology, 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 but have not really begun to be fully exploited. The power to analyse huge amounts of data rapidly, and to resolve questions in a very short period of time (questions that would previously have taken years of painstaking and very tedious research), has already had a dramatic impact on research and development in pharmacology, bio-pharmacology, 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 that 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 bio-pharmaceutical therapies, is being revolutionised. For instance, new therapies are being computer-designed to combat viruses based on modelling of the molecular structure of the virus and its interaction with human cells. Molecular biology is now a central discipline underpinning virtually all fields of medical research.

The downside of greater knowledge of disease and propensity for disease is greater scope for discrimination, which may take many forms, including reproductive discrimination, and loss of freedom and opportunity.

Many of the issues are to do with

- the collection of data or tissue and the presumptions involved in permitting data collection;
- how it may be used, including end-uses by third parties;
- security and confidentiality;
- maintaining the quality of information.

The significance of the new capacities in terms of benefits and implications for studied populations is only just beginning to be realized.

8. The Operation of Ethics Committees

8.1 Composition

Common mistakes made in the appointment of ethics committees, and which compromise their independence and capacity, are to appoint:

a) Lawyers who are associated with the law firm that represents the interests of the institution rather than lawyers who would have in mind the interests of research subjects;

b) Clinical and research professionals from within the institution who are likely, directly or indirectly, to be associated with the research projects of the institution;

c) 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;

d) A cleric or other representative of religion who has not studied the specialised areas of medical or research ethics;

e) No persons who represent the interests of those who are vulnerable to research, such as children, the aged, the developmentally disabled, or others who are disabled or have a mental or physical illness;

f) No person with a formal training in medical or research ethics.

8.2 Conflicts of interest

Conflicts of interest are often interpreted very narrowly to include pecuniary interests only. The Declaration of Helsinki also refers to such affiliations. There is a need to take into account direct and non-direct, pecuniary or non-pecuniary interests of members of ethics committees and their families, bearing in mind career and corporate or financial connections that may be particularly affected by a decision on a matter that is before the committee.

There is a need for the committee to have a method of dealing with conflicts of interest. Normally the process should be disclosure and voluntary exclusion while the item is being discussed, unless the committee itself sees reason to bring the person back into the discussion. Many committees simply have disclosure and not exclusion.

8.3 Accountability

Research ethics committees often deal with matters containing elements that, if disclosed, would compromise the commercial viability of a project by informing competitors. There is often a need to protect those interests simply for the sake of the viability of obtaining funding for research through development of the findings to a point that they have a commercial value.

However, commercial interests ought not to 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 those circumstances ethics committees may become a tool for social validation rather than genuine review.

Ethics committees should publish their proceedings. Matters of great commercial value might perhaps be edited out and only published 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.

8.4 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 opinion, and that reporting reflects the range of views of the members, including the opportunity for each member to have his or her individual dissent and the rationale for it recorded in the text or as an appendix, on request, and communicated in any report made.

8.5 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 have a training in an ethical discipline such as moral theology or moral philosophy. Often there are several different disciplines and there is a problem of language and culture.

In a secular context, there can be resistance to what is seen as moralising. For my own purposes I have categorised what I consider to be moral discussion stoppers. They are: a claim to moral pluralism, that people disagree on moral questions, a claim that one should not judge others, a claim that morality is a private matter, and 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 rigour like any other. (See appended table "Moral Discussion Stoppers").

The task for a Catholic on 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 recognised by reason, even by the reason of the unfaithful, and willingly chosen.

9. Bioethics Committees in Catholic Institutions

Bioethics Committees in Catholic institutions have a different function. Their role is to articulate a Christian response to the 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 that by saying that theology means:

- Thought and talk about God. Theology is about ourselves (and everything else) considered in relation to God
- Reflection upon the sources in which the truth of faith is articulated
- Natural theology or theodicy – philosophical theology – applying the light of reason
- Sacred theology – applying the light of faith

- Systematic theology seeks to determine the relationship between the truths of faith and other propositions which are not revealed.[25]

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, in the light of revelation and reason.[26]

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 finding itself 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 a morality about the individual, his or her 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.

In Christian teleology we seek communion with God and to develop in God's image and likeness. We 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.

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[25] Germain Grisez, The Way of the Lord Jesus Volume One: Christian Moral Principles Franciscan Herald Press 1983 p3ff.

[26] Servais Pinckaers OP, The Sources of Christian Ethics Catholic University of America Press, 1995.

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 (cf. Ex 33:18; Ps 27:8-9; 63:2-3; Jn 14:8; 1 Jn 3:2).

Pinckaers poses the question "What is Christian Ethics?"

- A science based exclusively on rational norms with revelation simply confirming and providing external inspiration?
- Based principally and sourced from Revelation?

For JP2 faith and reason are like the wings of an eagle – both 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?" and answers it. 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 of being rewarded for giving, but because being a giver is intrinsic to being happy.
- The central point of Christian morality is to act in a way that expresses our orientation towards God, because it is in acting in accord with our natures, (Image Dei) that we are happy.
- Obligation then is an expression of our vocation to be happy.

For Aquinas our purpose or end as human being 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 the attainment of enjoyment of that end and that happiness he thus creates in him or herself.

An ethics committee, within our tradition, then takes human dignity as a core notion. Dignity is intrinsic or inherent. It belongs to human beings simply by 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 the object of use. ❑