

# BIOETHICS MATTERS ENJEUX BIOÉTHIQUES

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## **Research on Human Subjects and the Culture of Life**

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Medical treatment is a part of most people's lives. Children receive vaccinations against life-threatening diseases, antibiotics for strep throat and ear infections and some may undergo surgery (and a general anesthetic) to have tonsils removed. In later life some people have physical therapy for injuries to joints, psychotherapy for emotional and/or mental difficulties, and take medicines for any number of ailments. Some people may face very serious medical problems that may require organ or tissue transplantation.

Behind all of these treatments and therapies has been research to improve practice and the lives of patients.

### WHAT IS RESEARCH?

Generally speaking, when people go to a doctor or health care facility, they expect that all interactions and interventions will be directed to their own wellbeing. They are seeking treatment or therapy. Sometimes patients will be asked if they wish to be part of a clinical trial or perhaps a study about a particular aspect of medical care. They are being asked if they are willing to participate in research.

While therapy is meant to benefit the patient directly, research has a very different focus. According to Robert J. Levine in his seminal

work, *Ethics and the Regulation of Clinical Research*, "The term 'research' refers to a class of activities designed to contribute to generalizable knowledge."<sup>1</sup> The aim of research is to collect information about a drug perhaps, or a type of treatment that will lead to a change in practice and eventually benefit others. Although the patient enrolled in the study might receive some therapeutic benefit, this is not the aim of research nor can therapeutic benefit be guaranteed. As Franklin G. Miller and Howard Brody put it, "Even though the patient may derive benefit from the treatment being evaluated, the basic goal of the activity is not personal therapy, but rather the acquisition of generally applicable scientific knowledge."<sup>2</sup> Those who agree to be part of a clinical trial or study are engaged in an altruistic act meant to benefit future patients.

### RESEARCH AND HUMAN SUBJECTS

A research project typically goes through several stages. Researchers must establish the question they hope to answer and propose a hypothesis (the answer they will be testing). They must develop the means and methods to test the hypothesis, work through their hypothesis on a theoretical level, then begin testing it. This might include lab work, experimenting with human cadavers and live animals.<sup>3</sup> If the research is directed to developing a medicine or intervention to be used on human patients, eventually the

research will have to involve human subjects. Here, governments, research ethics agencies and the Catholic Church have a special interest in protecting the wellbeing and dignity of human persons.

#### THE NEED FOR REGULATION

Research has always been a part of medicine but our modern interest in research ethics arose after the Second World War and the discovery of the Nazi atrocities which included scientific experimentation on human subjects. Under the Nazi regime, concentration camp inmates were used as nonvoluntary objects in research that exposed them to harm, suffering and even death, all apparently in the pursuit of scientific knowledge. Following the trials at Nuremberg, the Nuremberg Code was developed to safeguard the dignity of research subjects and protect them from undue risk of harm. The Declaration of Helsinki was a further reiteration of these principles.<sup>4</sup>

It should be noted, however, that research atrocities were not confined to Nazi Germany. In the United States, for instance, the infamous Tuskegee syphilis trial followed poor, rural, illiterate African American men even after the discovery that penicillin was an effective treatment for venereal disease. The men were neither told of nor offered the treatment and the trial was finally disbanded in 1972.<sup>5</sup> Children with mental and physical disabilities were enrolled in trials that involved deliberately infecting them with meningitis<sup>6</sup> or having them ingest radioactive material.<sup>7</sup> In these and other studies, vulnerable members of society were treated as objects and exposed to undue (and perhaps even unconscionable) harm, all in

the name of science. In the United States, this led to the Belmont Report, published in 1969<sup>8</sup> which articulated the need to preserve human dignity and protect research subjects. In Canada, research is governed by the guidelines set out in the Tri-Council Policy Statement now in its second edition.<sup>9</sup>

These and other guidelines are meant to ensure, among other things, the need to secure informed, voluntary consent from those participating in research studies<sup>10</sup> (consent that may be rescinded by the participant at any point in the trial),<sup>11</sup> and the need to protect those participants from undue risk of harm<sup>12</sup> — even to the point of stopping a trial if it becomes evident that the health of one group of participants is at risk if the study continues.<sup>13</sup>

#### THE CATHOLIC CHURCH AND RESEARCH ON HUMAN SUBJECTS

It is important to note that the Church is not opposed to medical research per se. In fact, Benedict XVI noted that the Church has had “constant support for research dedicated to the cure of disease and to the good of humanity throughout her 2,000-year-old history.”<sup>14</sup> Research is an expression of human intelligence and creativity that has the capacity to improve the lives of persons who are suffering. As well, research not only contributes to our technological and scientific knowledge, it helps us in our growth as moral beings.<sup>15</sup> In many ways, then, research is something that ought to be pursued and supported.

To be licit, however, medical research must have a “commitment to the truth and the common good....”<sup>16</sup> In this respect, justice must guide research insofar as investors’

interests in profits do not take precedence over all else and insofar as research is “pursued for the good of all, including those without means.”<sup>17</sup>

Pope John Paul II recognized the dangers of profit-driven research that chooses projects that will have the greatest financial yields and that might suppress knowledge in order to preserve those profits. He noted that such a perverted approach to research will deprive science “of its epistemological character, according to which its primary goal is discovery of the truth.”<sup>18</sup> And he warned against research that “harms human life and dignity or which ignores the needs of the world’s poorest peoples, who are generally less well equipped for scientific research.”<sup>19</sup>

According to Church teaching, research must ultimately recognize and respect the inestimable value of all human life at all stages of existence. In effect, researchers and scientists must realize that “The human being is not a disposable object, but every single individual represents God’s presence in the world.”<sup>20</sup> This applies to human persons already born and those who have yet to be born. Research must never engage in “the planned suppression of human beings who already exist even if they have not yet been born.”<sup>21</sup> To undertake manipulative and destructive research on embryonic human beings, for instance, cannot be justified no matter what knowledge might result from the experimentation. As John Paul II wrote, “methods that fail to respect the dignity and value of the person must always be avoided.”<sup>22</sup>

Ultimately the Church recognizes the promise that research holds and the ethical

challenges it faces. In this respect, the Church once again puts itself in the service of humankind. As John Paul II wrote to those engaged in health care and research, “As you face these [ethical dilemmas], I assure you of the Church’s desire to listen to you and to learn from your medical expertise and experience, and, at the same time, to share with you her own rich heritage of ethical teaching. Such dialogue ... can ensure that such research will truly contribute to the welfare of the person as a whole and to the integral development of society.”<sup>23</sup>

## CONCLUSION

Research is an essential component of health care and the use of human subjects is essential to research. While governments and research agencies now recognize the importance of respecting the dignity of human research subjects through the need for freely given informed consent to participate in studies and safeguards to protect research subjects from harm, their recognition of full human personhood is limited to those who are already born.<sup>24</sup>

The Church, acknowledging the many goods that come from research, insists on the value and protection of all human life at all stages of existence and that the goods of research be equitably distributed. In this way, the Church continues to promote a Culture of Life even in this area of health care. ■

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<sup>1</sup> Robert J. Levine, *Ethics and the Regulation of Clinical Research* (Baltimore: Urban and Schwarzenberg, 1981), p. 2.

<sup>2</sup> Franklin G. Miller and Howard Brody, "A Critique of Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials," *Hastings Center Report* 33 (2003), p. 22.

<sup>3</sup> The use of live animals in research is also an ethical concern. For Canadian guidelines, see: Canadian Council on Animal Care in Science/Conseil canadien de protection des animaux, "Ethics of Animal Investigation" [http://www.ccac.ca/Documents/Standards/Policies/Ethics\\_of\\_animal\\_investigation.pdf](http://www.ccac.ca/Documents/Standards/Policies/Ethics_of_animal_investigation.pdf) and "Social and Behavioral Requirements of Experimental Animals (SABREA)"

[http://www.ccac.ca/Documents/Standards/Policies/Social\\_and\\_behavioral\\_requirements.pdf](http://www.ccac.ca/Documents/Standards/Policies/Social_and_behavioral_requirements.pdf) .

<sup>4</sup> See Jessica Pierce and George Randels, *Contemporary Bioethics: A Reader with Cases* (New York: Oxford University Press, 2010): "Nuremberg Code", p. 507 and World Medical Association, "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects", pp. 515-519.

<sup>5</sup> See: Giselle Corbie-Smith, "The continuing Legacy of the Tuskegee Syphilis Study: Considerations for Clinical Investigation," *The American Journal of the Medical Sciences* 317 (1999), pp. 5-8 <http://simplelink.library.utoronto.ca/url.cfm/362857> (accessed May 2013); Vicki S. Freimuth, et. al., "African Americans' views on research and the Tuskegee Syphilis Study," *Social Science and Medicine* 52 (2001), 797-808 <http://journals1.scholarportal.info.myaccess.library.utoronto.ca/tmp/6008578159061964122.pdf> (accessed May 2013).

<sup>6</sup> This was an experiment conducted at the Willowbrook State School in the 1950s. See: Pierce and Randels, p. 489; David J. Rothman, "Were Tuskegee and Willowbrook 'Studies in Nature'?" *Hastings Center Report* (April 1982), pp. 6-7 <http://www.jstor.org/stable/3561798> (accessed May 2013).

<sup>7</sup> This was an experiment also conducted during the 1950's at Massachusetts' Fernald School. See: Doe West, "Radiation Experiments on Children at the Fernald and Wrentham Schools: Lessons for Protocols in Human Subject Research," *Accountability in Research* 6 (1998), pp. 103-125 <http://journals1.scholarportal.info.myaccess.library.utoronto.ca/tmp/9047444351767888507.pdf> (accessed May 2013).

<sup>8</sup> *The Belmont Report*: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

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<sup>9</sup> *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2010): [http://www.ethics.gc.ca/pdf/eng/tpcs2/TCPS\\_2\\_FINAL\\_Web.pdf](http://www.ethics.gc.ca/pdf/eng/tpcs2/TCPS_2_FINAL_Web.pdf)

<sup>10</sup> See the *Tri-Council Policy Statement*, p. 10; Nuremberg Code, #1; Declaration of Helsinki, #9, 10, 11.

<sup>11</sup> See the *Tri-Council Policy Statement* article 3.1.b, p. 28; Nuremberg Code, #9; Declaration of Helsinki, #9.

<sup>12</sup> See the *Tri-Council Policy Statement*, pp. 10-11; Nuremberg Code, #4,5,6,7; Declaration of Helsinki, #5,6,7.

<sup>13</sup> See the *Tri-Council Policy Statement* articles 11.4, 11.7, 11.9, pp. 157-163; Nuremberg Code, #10; Declaration of Helsinki, #7.

<sup>14</sup> Benedict XVI, "Address of His Holiness Benedict XVI to the Participants in the Symposium on the Theme, 'Stem Cells: What Future for Therapy?'" Organized by the Pontifical Academy for Life" (Sept. 16, 2006) [http://www.vatican.va/holy\\_father/benedict\\_xvi/speeches/2006/september/documents/hf\\_ben-xvi\\_spe\\_20060916\\_pav\\_en.html](http://www.vatican.va/holy_father/benedict_xvi/speeches/2006/september/documents/hf_ben-xvi_spe_20060916_pav_en.html) (accessed April 2013).

<sup>15</sup> *Ibid.*

<sup>16</sup> John Paul II, "Letter of John Paul II to H.E. Msgr. Jozef Kowalczyk Participating in the International Conference on 'Conflict of Interest and its Significance in Science and Medicine (Warsaw 5-6 April 2002'" (March 25, 2002) [http://www.vatican.va/holy\\_father/john\\_paul\\_ii/letters/2002/documents/hf\\_jp\\_ii\\_let\\_20020411\\_conference-poland\\_en.html](http://www.vatican.va/holy_father/john_paul_ii/letters/2002/documents/hf_jp_ii_let_20020411_conference-poland_en.html) (accessed April 2013).

<sup>17</sup> *Ibid.*

<sup>18</sup> *Ibid.*

<sup>19</sup> *Ibid.*

<sup>20</sup> Benedict XVI, "Address" (Sept. 16, 2006).

<sup>21</sup> *Ibid.*

<sup>22</sup> John Paul II, "Address of the Holy Father John Paul II to the 18<sup>th</sup> International Congress of the Transplant Society" (August 29, 2000) [http://www.vatican.va/holy\\_father/john\\_paul\\_ii/speeches/2000/jul-sep/documents/hf\\_jp-ii\\_spe\\_20000829\\_transplants\\_en.html](http://www.vatican.va/holy_father/john_paul_ii/speeches/2000/jul-sep/documents/hf_jp-ii_spe_20000829_transplants_en.html) (accessed April 2013).

<sup>23</sup> John Paul II, "Address of John Paul II to the Participants in the International Congress of Cancer and Hormones" (April 26, 1986) [http://www.vatican.va/holy\\_father/john\\_paul\\_ii/speeches/1986/april/documents/hf\\_jp-ii\\_spe\\_19860426\\_congreso-cancro\\_en.html](http://www.vatican.va/holy_father/john_paul_ii/speeches/1986/april/documents/hf_jp-ii_spe_19860426_congreso-cancro_en.html) (accessed April 2013).

<sup>24</sup> See *Tri-Council Policy Statement*, Chapter 12, Section E, pp. 176-180.