



Charles Darwin *In Memoriam*

Evolutionary looks at the why of biological and cultural phenomena.

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Abuse of Informed Consent

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ABSTRACT: Informed consent is one of the great ethical achievements of humanity, but it is not always ethical to demand it. It is made to protect people who are subjects of experimentation, or who give private information for scientific research. It should only be required when at least one of these conditions exists.

KEYWORDS: Nuremberg Code, Declaration of Helsinki, biomedical research, ethics committee.



Informed consent:
Do you sign it or
do you read it?

Cartoon: <https://bit.ly/2WMCeZY> reproduced with permission (Dr. M. J. Herraiz).

Darwin began to analyze ethics and morals from the evolutionary point of view in 1838, in his *Notebook of Metaphysical Notes*, formally publishing his analyzes in 1871 in *The Origin of Man* (Allhoff, 2003). His feelings about the experimental subjects are eloquent: "Vivisection ... is a subject which makes me sick with horror, so I will not say another word about it, else I shall not sleep to-night" (*Correspondence* vol. ER Lankester, 22 March 1871, <https://www.darwinproject.ac.uk>).

But long before the monstrous vivisections that made Darwin suffer, humans have suffered through immoral "medical" practices, ranging from the vivisection of classical antiquity to indefensible experiments in more recent times, like the crimes of Josef Mengele and Shirō Ishii during World War II (Rupke, 1987; French, 2001).

In addition to testing new drugs in poor populations from Australia, Canada and Africa, with "control groups" that were not given the necessary treatment, in Latin America we are particularly close to the collaboration of the Guatemalan government with the Public Health Service of the USA, a project in which hundreds of Guatemalans were infected with gonorrhea and syphilis during the mid 20th century (McNeil, 2010)

In order to put an end to such abuses and crimes, standards such as the 1947 Nuremberg Code and the 1964 Declaration of Helsinki were signed. Both include the idea that people who participate in experiments must **understand** their implications (discomfort, dangers, responsibilities and alternatives) and freely **agree** to participate. The set of both ideas are called "informed consent".

However, in inadequate hands, the idea of informed consent can become harmful, instead of decent and beneficial, and I realized this problem when a friend told me of a problem his daughter had when she proposed, her school's Science Fair, a project about eye color in her class.

When she presented the idea, the teacher told her that she needed informed consents signed by the parents. For someone who knows what informed consent is about, it should be clear that neither was the project about subjecting the children to an experiment, nor was it about the girl profiting from selling private information about eye color in her classroom. Therefore, it was inappropriate to ask for informed consent, although of course children were free to refuse participation.

Moving from the curious school example to the research world, the equivalent of the teacher with good intentions, but incompetent to decide in this field, are politicians and bureaucrats who have gone from the extreme of allowing abuses, to the extreme of setting unnecessary requirements or even banning all biomedical research. This is not new; Darwin himself expressed fear of ignorant politicians deciding on science (Allhoff, 2003).

In 2002, an interesting case occurred in Costa Rica. It was denounced that government regulations allowed private companies to experiment in the country, patent their findings in other countries, and obtaining enormous economic benefits without sharing them with the country or with the experimental subjects (Castellón, 2002).

As a result of the outcry, 124 clinical trials and 235 epidemiological studies were suspended, and for 15 years it was illegal to do biomedical research in Costa Rica (Oviedo, 2013; Guerrero, 2015). Biomedical research was also demonized by the Costa Rican media, and I know researchers who were so vilified that they abandoned research with human altogether. We will never know how much this extremist period of Costa Rican politics affected healthcare.

Finally, in 2014, Law 9234 was approved and one year later, its corresponding regulation was made public (*La Gaceta*, 2015). Currently, Costa Rican law requires informed consent, prior approval by an institutional ethics committee, and proper data management throughout the entire study. This law distinguishes among studies in which *something is done to the patients* and those in which *they are only observed*, and considers insurance policies and compensations (Guerrero, 2015). In short, it is a good law (too bad it took so long to come up with something so full of common sense and so necessary).

In summary, informed consent is made to protect people who are subjects of experimentation, or who give private information for scientific research. It should only be required when at least one of these conditions occurs. In other cases, like that of the girl in this story, neither is it ethical to ask for it, nor is it correct to accede to a requirement that is, simply and clearly, just a fruit of ignorance.

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EDITED BY: Carolina Seas and Priscilla Redondo.

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