Informed Consent

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A consent form is, in its simplest definition, a contract between an individual and a researcher. It is usually associated with investigations related to health and human biology. For that matter, it dwells between two spheres, the law and bioethics. Consent is the willingness to be part of an experimental trial or to accept a medical treatment. However, informed consent is much deeper than an acceptance. As its name implies, it requires information and it is more detailed. It is not simply signing a paper. From the subject point of view, it is about reading, learning, and understanding what to expect. It is about comprehending the alternatives, as well as the risks and the consequences -physical or psychological- from being part of the research or medical procedure.

There are authors, like Getz, who affirm that informed consent might be described as a "Bill of Rights" and it demands to include certain principles. First, and foremost, consent has to be given voluntarily and free of any kind of manipulation or coercion. Because we are talking about informed consent, research subjects must receive all information possible about the study, specially if there are risks. More than that, the researcher must be sure the subject understands the information that is being given to her. To guarantee that the subject comprehend the investigation, the information provided has to be written in an understandable way to the individual and she must not be under the effect of alcohol or drugs. Additionally, she has to have enough time, within the circumstances, to make a decision whether to agree with the consent or not. There are also other variables affecting informed consent like age and disabilities. In that case, the researcher or practitioner should take steps to make sure the appropriate channels are taken and the necessary authorizations are in place. In short, informed consent is, in its core, not

a simple form, but a communication process that guarantees a subject's full understanding of his decision to participate or not in an experimental trial or medical procedure.

The Declaration of Helsinki, in the mid 60s, focused in the importance of consent in the areas of research. Later, The Belmont Report, issued by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research in the US, recognized the rights of the subjects in an experimental trial in 1978. The report is considered the foundational writing on ethics of human subject research. The establishment of the Commission and the written report was triggered by a series of "denounced medical experiments, culminating in the infamous Tuskegee Syphilis Study" (Adashi, 1345). One of the principles stated in this document was the "respect for persons" -being the other two beneficence and justice-. Under the respect premise, the report required a a non exculpatory voluntary "informed consent."

40 years later, the Belmont "report principles have permeated clinical medicine [...] they are part of a broad cultural shift that has dramatically reworked the relationship between doctor and patient" Cassell (12) The informed consent has provided protection to patients by allowing them to play a significant role in their own health decisions and risk assessments.

The original principles in the report have evolved. Nowadays, medical services are not provided only by doctors, but health organizations. Informed consent it is not only about treatments, it is also about collateral but equally important factors like costs, population health, an even health disparities. Informed consent has forced the biological sciences to offer subjects truthful information and full disclosure of risks and benefits on which they may base their decisions, not only as individuals but as members of their communities.

In our modern dynamics, trends in “healthcare should strive to transparency” (Campbell, 63) and disclosure. This brings to the front issues of fairness and equity as part of the process to help subjects make informed decisions and allow self-determination. As Studdert (975) writes “optimal treatment choices require marrying evidence of clinical efficacy and risk with the values, preferences, and goals of individual patients.”

Decades have passed since the horrible years of the Tuskegee study. Law and bioethics have walked a long path to avoid something like that could happen again. Full disclosure and truthful information from researchers, as well as subjects effort to understand the importance of making their own decisions are the fundamental pillars for protecting the health and well-being of our communities.

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