Informed Consent in Human Subject Testing: Definition and Status under International Law

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In this Article of ethical considerations, human subject testing, especially with regard to pharmaceutical drugs, is explored. The Article traces the origins and developments of informed consent in the development of ethical guidelines in human research and pharmaceutical regulation. The Author also expounds on the principles of human subject testing with special concerns on the rights of test subjects and obligations of researchers, respect for autonomy and bodily integrity of persons, beneficence, and justice, as well as minimum ethical standards in vaccine trials.

The Author then enumerates the instances of defining informed consent under International Law: the classification under Article 38 of the Statute of the International Court of Justice, treaties, customs, and general principles of law, with reference to the HIV/AIDS pandemic, the participation of vulnerable and special populations, and *erga omnes* obligations.

Lastly, the Author analyzes the definition of informed consent vis-à-vis the minimum standards on informed consent revolving around information disclosure, capacity to give and voluntariness of consent, and the argument of cultural relativism.