

*“The object of philosophy is the logical clarification of thoughts. Philosophy is not a theory but an activity.”*

*- Ludwig Wittgenstein*

## News

- Aug 4th, Missourians will have the opportunity to vote [#YesOn2](#) to expand Medicaid in Missouri. Visit [yeson2.org](#) to learn more about this important effort to bring healthcare to hardworking Missourians.
- Aug 17th, The Center for Practical Bioethics will host the 26th Annual Flanigan Lecture, a live online event 6:45 PM CDT – 8:00 PM CDT:
  - A Letter to My People: Reflections on Whiteness Amid a Racial Reckoning in America
  - Erika Blacksher, PhD, John B. Francis Chair, Designee

## Hot Topic

### The Development and Future of Informed Consent

In bioethics, along with many other fields, there are two causes of instrumental change. The first comes about through proactive measures. This involves individuals or groups with ideas and foresight that work to make changes and improvements to move society, an organization, etc. in the arguably better direction. The second cause of change is reactionary. This when an event or sequence of events occur that cause a reaction, typically through policy or culture change, so those events do not occur again.

The history of bioethics is a long combination of proactive measures and reactionary corrections, with medical ethics typically acting proactively through oaths and principles, and research ethics reacting to atrocities done to other persons.

#### From Reactive to Proactive

But these causes cannot be split cleanly, since some reactionary measures turn out to be the foundations of insightful proactive actions. The history of informed consent exemplifies this sequence.

From an ethical perspective, the concept of consent is derived from the ethical principle of autonomy (Beauchamp & Childress). In the popular mind, medical ethics began in Ancient Greece with Hippocrates and the Hippocratic Oath. This perception, however severely fails to address informed consent in the modern understanding, which advises the practitioner to “XVI Perform all this calmly and adroitly, concealing most things from the patient while you are attending to him” (Hippocrates, vol 2. 1923, p. 297).

A more appropriate beginning of informed consent can be traced to the Enlightenment writings of Benjamin Rush and Thomas Percival. But Rush and Percival give an incomplete understanding of modern informed consent, as they argued that informed consent was just an aspect of being a good physician. This is made clear with Rush advising physicians to “yield to them [patients] in matters of little consequences, but maintain an inflexible authority over them in matters that are essential to life” (Rush, medical inquiries and observations), and also saying, “The obedience of a patient, to the prescriptions of his physician, should be prompt, strict, and universal” (Rush, On the duties of the patient to their physician).

While the development of informed consent in the clinical setting has been proactive work through Rush and Percival, its development in the research setting has been mostly reactive. Responses to the issue of informed consent in the research setting have mostly arisen from controversial cases and the understood need to develop

something to help prevent these situations in the future. These responses include but are not limited to the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report.

## The Nuremberg Code

Coming about from crimes committed by Nazi physicians during the Second World War, and the decision in *United States v. Karl Brandt*, the Nuremberg Code was the first major set of ethical limitations on research (Beauchamp & Faden, 1986, p. 153). Principle One of the Code states, "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." While not directly stating the words *informed consent*, the three qualifications for informed consent, as stated at the beginning of this paper, are stratified in Principle One. The person engaging in the research must be voluntary, informed, and not coerced into that decision.

## The Declaration of Helsinki

Following the Nuremberg trials and their revelations, the World Medical Association (WMA) felt that in response a code of ethics would be required. This was formalized in 1964 with the Declaration of Helsinki (World Medical Association, Declaration of Helsinki, 2001). The Declaration of Helsinki establishes what constitutes ethically permissible research, outlining principles which researchers (as established by the Declaration who qualifies as researchers) must follow. Among these include explicit direction for obtaining informed consent in Principle 20 which states, "the subjects must be volunteers and informed participants in the research project" (p. 374). These are the first widely published guidelines that directly require participants be *informed* when consenting to participate in research in order for it to be considered ethical.

## The Belmont Report

One can argue that The Belmont Report (1979) was the last major step towards the modern understanding of informed consent. Created as a direct response to the Tuskegee Syphilis Study, which is described as, "the most notorious case of prolonged and knowing violation of subjects' rights to emerge" (Beauchamp & Faden, 1986, p. 165). In it, 400 Black male participants knew not the name nor the aspects of their disease as physicians monitored the effects of untreated syphilis for decades, even after known treatments became available. (Beauchamp & Faden, 1986). When the study became known to the public, a national commission, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, was established, which produced The Belmont Report.

The commission was charged to examine not only *biomedical* research but *behavioral* research as well (Beauchamp & Faden, 1986, p. 167). This married the two types of research together under the same governing principles moving forward in the United States. The Belmont Report established three ethical principles: Respect for Persons, Beneficence, and Justice (Belmont Report). Each of these three principles directly apply to their practical application, Respect for Persons (later understood as Respect for Autonomy) to Informed Consent, Beneficence relates to Risk-Benefit Assessment, and Justice to the Selection of Subjects (Beauchamp & Faden, 1986, p. 216). This combination gave philosophical support to practical guidelines, thereby not only establishing processes for uphold patient rights but the ethical principles that those rights are founded upon.

## What We Can Learn

These previous events demonstrate two major points that should be kept in mind:

1. It would be difficult to argue that the actions taken because of the Nazi experiments, Tuskegee Syphilis Study, etc. are not beneficial to the field of bioethics. But I would argue that it would be better if those atrocities had not

happened at all. Reactionary responses can clearly be beneficial, but they still imply the occurrence of events that require reaction, which is not the ideal.

2. Patient informed consent needs to be fully present before research can ethically be conducted. Also, as argued earlier, informed consent cannot be coerced. Therefore, mandates involving health need to be extremely considered before implemented and enforced. It would be ideal to avoid ethical violations today that require reactionary efforts later.

## Bioethics in the News

[How Do Moral Philosophy Courses Affect Student Behavior?](#)

[Bioethics and practical justice in the post-COVID-19 era](#)

[Bioethicist On Libertarian Views Toward Face Mask Laws](#)

[Who should get the Covid-19 vaccine first? It's way trickier than you might think](#)

[Ethics Consult: Is a COVID Human Challenge Trial Ethical? MD/JD Bangs Gavel](#)

## Case Study

The patient is a 44-year-old male, suffering from complications from an aggressive form of cancer. The patient's condition has continued to worsen, with treatments not as effective as expected, and now expectations are low. The patient is non-responsive but does have a completed advance directive, which states that aggressive measures should cease if there not a high expectation of meaningful recovery. It also lists his wife as surrogate decision maker, which she is doing. The patient is currently on GIP (general in-patient hospice).

It was recently brought to the surrogate decision maker's attention that there is a new clinical research trial available that the patient would likely qualify for. The research is new, so the short-term and long-term risks and benefits are not fully known. While there is a possibility of improvement for the patient, there is expected to be discomfort and quality of life impacts. It is agreed that the likelihood of full recovery is low. The patient's attending physician and oncologist agree that the research may be beneficial. Initial, the patient's wife agreed but after reflection is now stating that she is not sure if that is the right decision. The advance directive does not outline anything related to research. Since the patient has not expressed anything relating to research either, the patient's wife is worried whether it is in his best interest and would he have agreed to participate.

The patient's wife and attending physician are both requesting an ethics review.

## Ethical Musings

### The Dynamics of Power

The nature and reality of Truth has been examined and debated for centuries. An example of this is the debates in fifth century BCE between *nomos* (laws) versus *phusis* (nature), which examines whether ethics and morality exist outside of humans or whether they are created by humans.

The debate is often described as the difference between objective morality and subjective morality. Or another way of asking if morality is true regardless of human and society, or is morality completely subjective to the people who create it? This conflict between objective and subjective is connected to the question, what is objective truth? All of which is connected to the dynamics of power.

## Law as a Response to Human Nature

This is demonstrated in Plato's dialogue *Gorgias*, in which Socrates argues with Gorgias (after whom the dialogue is named) regarding the nature of laws. Gorgias and his student Callicles argue that "conventional morality was invented by the weak to protect themselves against the strong, inhabiting the latter from doing what by nature they have a right to do, which is to use their inferiors for their convenience" (Grayling, p. 54). Essentially, laws were created to protect humans from true human nature, a true human nature that is brutal. True morality exists as animals in the wild exist. A lion is not ethically wrong for hunting and eating the gazelle. That is its nature and it would be wrong for the lion to not hunt the gazelle. But say the animal kingdom organized and the gazelles passed laws that made it illegal/wrong for lion to hunt gazelles. What should the lion do?

This is the argument by Gorgias: that our nature dictates what should be seen as right and wrong, not the laws and ethics human create (If you are thinking this sounds similar to Nietzsche and the *ubermensch*, it is not dissimilar but also not really that same argument). Socrates rejects this argument, believing in an objective good and the benefits of learning philosophy and dialoging with others to find the truth. But following the argument of Gorgias, the next question becomes: What is the true nature of humans?

## What is Human Nature

In the Platonic dialogues, specifically *The Republic*, it is almost agreed that most men are not very good at all. This is exemplified in the thought experiment of the Ring of Gyges, which is a story of a man who finds a ring that allows him to become invisible. So granted this awesome power, how did the man react? "...he at once arranged to become one of the messengers sent to report to the king. And when he arrived there, he seduced the king's wife, attacked the king with her help, killed him, and took over the kingdom" (*Republic*, 360). This is furthered in a more detailed thought, which goes:

*"Suppose now that there were two such magic rings, and the just put on one of them and the unjust the other; no man can be imagined to be of such an iron nature that he would stand fast in justice. No man would keep his hands off what was not his own when he could safely take what he liked out of the market, or go into houses and lie with any one at his pleasure, or kill or release from prison whom he would, and in all respects be like a god among men.*

*Then the actions of the just would be as the actions of the unjust; they would both come at last to the same point. And this we may truly affirm to be a great proof that a man is just, not willingly or because he thinks that justice is any good to him individually, but of necessity, for wherever any one thinks that he can safely be unjust, there he is unjust.*

*For all men believe in their hearts that injustice is far more profitable to the individual than justice, and he who argues as I have been supposing, will say that they are right. If you could imagine any one obtaining this power of becoming invisible, and never doing any wrong or touching what was another's, he would be thought by the lookers-on to be a most wretched idiot, although they would praise him to one another's faces, and keep up appearances with one another from a fear that they too might suffer injustice."*

— Plato, *Republic*, 360b–d

## The Power of Self-Interest

Plato's main argument is that, when given great power, it is assumed most men will act in his/her own self-interest, not follow any laws or morals, and act in many ways unethically. This is because of the fear of repercussion, either through punishment or loss of reputation, that would happen if someone was known to be doing unethical acts.

This comes back to the argument of Gorgias, that power dynamics are the reason for the creation of morals and laws. If a person had the power to do anything without fear of repercussions, why would we assume he/she would act morally? This also touches the extensive work by Foucault on the different aspects of power and its dynamics (but we will address that in another dispatch so that it may receive the proper attention).

The point that you should keep in mind during these challenging times is the interplay between morality, humanity, and the power dynamic between them. If there is no objective morality, then right and wrong is determined by those with the power to impose their will.