5.3: Experimental Ethics

Experiments with human subjects are technically hard to do, as we have just seen, because of things like the Placebo Effect. Even beyond these difficulties, they are hard because human subjects just don't do what we tell them, and seem to want to express their free will and autonomy.

In fact, history has many (far too many) examples of experiments done on human subjects which did not respect their humanity and autonomy – see, for example, the Wikipedia page on **unethical human experimentation** .

The ethical principles for human subject research which we give below are largely based on the idea of respecting the humanity and autonomy of the test subjects, since the lack of that respect seems to be the crucial failure of many of the generally acknowledged unethical experiments in history. Therefore the below principles should always be taken as from the point of view of the test subjects, or as if they were designed to create systems which protect those subjects. In particular, a utilitarian calculus of *the greatest good for the greatest number* might be appealing to some, but modern philosophers of experimental ethics generally do not allow the researchers to make that decision themselves. If, for example, some subjects were willing and chose to experience some negative consequences from being in a study, that might be alright, but it is never to be left up to the researcher.

"Do No Harm"

The Hippocratic Oath, a version of which is thought in popular culture to be sworn by all modern doctors, is actually not used much at all today in its original form. This is actually not that strange, since it sounds quite odd and archaic[11] to modern ears – it begins

> *I swear by Apollo the physician, and Asclepius, and Hygieia and Panacea and all the gods and goddesses as my witnesses that...*

It also has the odd requirements that physicians not use a knife, and will remain celibate, *etc.*

One feature, often thought to be part of the Oath, does not exactly appear in the traditional text but is probably considered the most important promise: **First, do no harm** [sometimes seen in the Latin version, **primum nil nocere**]. This principle is often thought of as constraining doctors and other care-givers, which is why, for example, the *American Medical Association* forbids doctors from participation in executions, even when they are legal in certain jurisdictions in the United States.

It does seem like good general idea, in any case, that those who have power and authority over others should, at the very least, not harm them. In the case of human subject experimentation, this is thought of as meaning that researchers must never knowingly harm their patients, and must in fact let the patients decide what they consider harm to be.

Informed Consent

Continuing with the idea of letting subjects decide what harms they are willing to experience or risk, one of the most important ethical principles for human subject research is that test subjects must be asked for **informed consent**. What this means is that they must be informed of all of the possible consequences, positive and (most importantly) negative, of participation in the study, and then given the right to decide if they want to participate. The information part does not have to tell every detail of the experimental design, but it must give every possible consequence that the researchers can imagine.

It is important when thinking about *informed consent* to make sure that the subjects really have the ability to exercise fully free will in their decision to give consent. If, for example, participation in the experiment is the only way to get some good (health care, monetary compensation in a poor neighborhood, a good grade in a class, advancement in their job, *etc.*) which they really need or want, the situation itself may deprive them of their ability freely to say *no* – and therefore *yes*, freely.

Confidentiality

The Hippocratic Oath does also require healers to protect the privacy of their patients. Continuing with the theme of protecting the autonomy of test subjects, then, it is considered to be entirely the choice of subject when and how much information about their participation in the experiment will be made public.

The kinds of information protected here run from, of course, the subjects' performance in the experimental activities, all the way to the simple fact of participation itself. Therefore, ethical experimenters must make it possible for subject to sign up for and then do all parts of the experiment without anyone outside the research team knowing this fact, should the subject want this kind of privacy.

As a practical matter, something must be revealed about the experimental outcomes in order for the scientific community to be able to learn something from that experiment. Typically this public information will consist of measures like sample means and other data which are *aggregated* from many test subjects' results. Therefore, even if it were know what the mean was and that a person participated in the study, the public would not be able to figure out what that person's particular result was.

If the researchers want to give more precise information about one particular test subject's experiences, or about the experiences of a small enough number of subjects that individual results could be *disaggregated* from what was published, then the subjects' identities must be hidden, or **anonymized**. This is done by removing from scientific reports all *personally identifiable information [PII]* such as name, social security or other ID number, address, phone number, email address, *etc*.

External Oversight [IRB]

One last way to protect test subjects and their autonomy which is required in ethical human subject experimentation is to give some other, disinterested, external group as much power and information as the researchers themselves. In the US, this is done by requiring all human subject experimentation to get approval from a group of trained and independent observers, called the **Institutional Review Board** [**IRB**] *before the start of the experiment*. The IRB is given a complete description of all details of the experimental design and then chooses whether or not to give its approval. In cases when the experiment continues for a long period of time (such as more than one year), progress reports must be given to the IRB and its re-approval sought.

Note that the way this IRB requirement is enforced in the US is by requiring approval by a recognized IRB for experimentation by any organization which wants ever to receive US Federal Government monies, in the form of research grants, government contracts, or even student support in schools. IRBs tend to be very strict about following rules, and if the ever see a violation at some such organization, that organization will quickly get excluded from federal funds for a very long time. As a consequence, all universities, NGOs, and research institutes in the US, and even many private organizations or companies, are very careful about proper use of IRBs.
