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Informed Consent in Biomedical Research

Daphné Townsend, Master's student, School of Information Technology and Engineering,
University of Ottawa, Ottawa, ON, Canada

***Abstract* – A course that teaches critical thinking and awareness of the ethical decision process can help ensure that rapidly emerging technologies have a positive impact on our society. When studying ethics in biomedical engineering, a topic such as research methods for experiments involving human beings cannot be overlooked. A well-constructed informed consent (IC) form is one of the basic building blocks of ethically conducted research because it provides the patient with sufficient information to autonomously make a decision in accordance to their values. Informed consent is one of numerous topics addressed in the ethics course offered at the University of Ottawa and Carleton University.**

Index Terms – Biomedical research, biomedical ethics, informed consent, fraud, ethics course

I. Introduction

As the field of biomedical engineering gains in popularity, the number of sub-fields it encompasses is constantly expanding. This new kind of engineer, the biomedical engineer, is "trained to work at the intersection of science, medicine, and mathematics to solve biological and medical problems", and will be faced with many technical, intellectual, social and ethical challenges during the course of his or her career [1].

Incidents of research misconduct are easy to find, whether it be the falsification of data, exclusion of women or minorities in a study, use of sub-standard materials or even the fabrication of entire studies. As recently as January 2006, the CBC News aired a three part investigative report on the scientific scandal involving Dr. Ranjit Kumar Chandra, formerly of the Memorial University in St. John's, Newfoundland [2]. The report recounts stories of alleged lost data, studies that experts believe were made up, participants who did not exist, as well as the barriers faced by Dr. Chandra's research nurse, Marilyn Harvey, as she in tried to bring the fraud to the attention of the university's directors. CBC News comments that the case of Dr. Chandra, by revealing "just how easy it is to get away with fraud", may have finally transmitted to universities and journals the urgency of addressing the issues of fraud, and the measures that must be in place to protect whistleblowers from intimidation tactics [2].

While the scandal involving Dr. Chandra was unfolding in Canada, Oslo's Norwegian Radium Hospital had started appointing members for an independent review commission [3]. A prominent scientist, Dr. Jon Sudbo, had verbally admitted he "completely fabricated a paper published last year in The Lancet associating long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) with a lower risk of oral cancer" [4]. He had fabricated data for over 900 participants; their age, weight, birthrate and drug use, and convinced the co-authors it was genuine [4]. The cases of Dr. Chandra and Dr. Sudbo are some of the few incidents of fraud that reach the public.

A course that teaches critical thinking and awareness of the ethical decision process to engineering students can help ensure that rapidly emerging technologies have a positive impact on our society and are designed with "socially responsible and ethically sound practices" [5]. Starting in September 2006, a course titled *Ethics, Research Methods and Standards for Biomedical Engineering* will be one of two mandatory courses for the undergraduate biomedical engineering program at the University of Carleton in Ottawa, Ontario.

II. Informed Consent

When studying ethics within the biomedical engineering context, a topic such as research methods for experiments involving human beings cannot be overlooked. When conducting such research, obtaining the informed consent (**IC**) of study participants is absolutely indispensable. When analyzing the issue of IC from different perspectives, one can see that it is ethically justifiable and even necessary according to numerous ethical theories.

The patient's right and the researcher's obligation to IC are now seen as a regular occurrence and a requirement for publication to a respected journal. Unfortunately, this was not always the case. Before the Nuremberg Code of 1947, doctors could use the Utilitarianism Theory to argue why consent should not be required and how it could even delay the advancement of scientific knowledge [6]. The (paternalistic) mentality at the time was that doctors and researchers knew best, and that informing patients would only serve to disconcert them. However some scientists, doctors and members of other professions such as lawyers and philosophers rejected that line of thought because patients were human being foremost and had the right to self-determination.

III. Origins of Informed Consent

In an academic sense, the first principle of the Nuremberg Code, and the 23rd of the Declaration of Helsinki stipulate strict ethical guidelines mandating IC. This ethical sentiment has been expressed prior to their

elaboration, based on philosophical, religious and legal grounds.

A. *Philosophical*

1) Hippocratic Oath: There are numerous philosophical arguments in the favour of requiring IC for all research activities involving humans. Reasoning based on the Hippocratic Oath is often used. The Oath states that doctors should firstly help and secondly do no harm. IC would inform patients of a doctor's intention and provide feedback to the doctor about what patients consider 'help' and 'harm' to their physical and psychological condition. For example, a patient might prefer a less aggressive but lengthier treatment when a doctor might have thought a shorter but more radical one was better. U.S. public policy has consistently affirmed that "competent persons are generally the best protectors of their own well-being" [6]. This further supports the use of consent forms to ensure the actions of the doctor or researcher to be beneficial.

2) Society's Greater Benefit: Research involving humans is only conducted when the particular question cannot be answered without human experimentation. This kind of research may happen only if it would provide greater benefits to society than potential harm to the participants. For guidelines on this as well, we can refer to the Nuremberg Code, and the Helsinki Declaration of 1964.

The theory that ensuring IC of the patient will ultimately produce benefits to society relies on the thought that providing patients with information will reduce their suspicions about research activities. This is also supported by the Utilitarianism Theory developed by John Stuart Mill [7]. Patients having more confidence and knowledge about the studies would be more willing to participate and this would have the additional benefit of increasing the speed as which studies are completed. The downfall of this theory is that taken to the extreme, one could argue that greater societal benefit could be attained by not bothering with the time consuming process of providing each individual with information about the study and allowing them the choice of participation. This example displays how the Utilitarianism Theory tends to remove human sentiment from decisions.

B. *Religious*

Many religions have an implicit or explicit requirement for IC based on the duty to treat each other and each other's body with respect and not to interfere in another's private matters without their consent.

C. *Legal*

Originally, patients could bring a claim of battery, touch without consent, against physicians. In this case, the patient did not have to prove harm. We have moved away from battery to focus on negligence and malpractice. Currently, the failure to obtain proper consent is treated as negligence. However, this legal definition of negligence means that the doctor or researcher had a duty towards the patient, and that the patient was harmed directly due to a breach in that duty or from actions that resulted directly from it. It would seem that there are more laws punishing the lack of IC rather than formulating the legal obligation. IC forms are there to ensure the patient agrees to be studied or examined according to a known protocol.

IV. Purpose of Informed Consent

There are many functions of informed consent and they range from protecting the researchers to encouraging good decision making. A well-constructed IC form is one of the basic building blocks of ethically conducted research because it provides the patient with sufficient information to autonomously make a decision in accordance to their values. It also allows for greater transparency and for physicians and other persons in authority to scrutinize the research and its potential benefits and harms. Researchers may see IC forms as limiting their liability and that of their institution. In general, IC forms are there to protect the patient's interests by ensuring the appropriateness of research and the safety of the participants.

Safeguards must be in place to ensure the forms are not misused. For example, one would not want an employer or an insurance company asking hospitals for copies to discover which tests, pharmaceuticals or procedures a person has been subjected to and what the results revealed.

V. Consent in the Nuremberg Code

The Nuremberg Code, which was the basis for the Declaration of Helsinki that was implemented in law in 1964, is a list of ten principles of human experimentation.

The voluntary consent of the human subject is absolutely essential [6]. This first principle is expanded in two paragraphs, which relate specifically to consent.

A. *Competence*

The first issue of consent addressed by the Nuremberg Code is the legal capacity of the person surrendering his or her consent. This is strongly tied to the notion of competence. In order to give their valid and voluntarily signed IC persons must be able to understand what the study encompasses, properly evaluate the benefits and side effects, and understand how the consequences would affect their personal situation. They must be able to weigh the alternatives and come to a rational decision based on their values and objectives.

Reasons for which persons would be deemed incompetent to give their consent are the same as would make them incompetent in the legal sense. For example, it would be unethical to use children in a study, no matter how harmless, without their guardian's explicit IC and if possible the child's.

The assessment about a person's competence must be closely balanced with that person's right to self-

determination: their right to make their own choices about their life and their body, based on their personal values.

B. *Authentic Choice*

The principle of authentic choice signifies that the person considering taking part in scientific research should be, among other things, free to decide whether to consent or not. The scientific personnel should not coerce or influence that person in any way including "any element of force, fraud, deceit, duress" by direct or indirect methods [6]. This statement becomes more important when a potential subject is susceptible to coercion due to poverty, subordination or any other physical, social (dependency) or psychological condition. Take for example prisoners being recruited for a study: it is never possible to know if prisoners have given their educated and informed consent or if they volunteered by fear of repercussions or in the hope of ingratiating themselves to a superior to show 'good behaviour'. Although the consent given might still be voluntary, coercion might affect the patient's reasoning and force them into a different decision they would not have made otherwise. For example, a physician's implied promise of better or worse treatment in the prison depending on participation in the study would be considered indirect coercion and be in breach of the Nuremberg Code [8].

Remuneration for participation in unpleasant experiences can constitute coercion. If remuneration is too low, participants may decline, however a high remuneration may force impoverished participants to join the study because they have no other mean of generating that much money.

C. *Disclosure*

In addition to being legally competent, a person must be provided with sufficient information to be able to understand all implications of the study. Withholding any information such as side effects or duration of the study by a researcher to avoid dissuading participants would constitute a breach of ethics according to the Nuremberg Code. In order to make an educated decision, a person must be provided with information in many areas and these are now regulated by federal laws in the U.S. These include any alternative therapies available (if applicable), an explanation of availability of treatment for injuries or disabilities resulting from the study, extent of confidentiality and special sections explaining potential risks to a participant's foetus for pregnant women.

What constitutes 'sufficient information' used to be defined by the physician's point of view, but recently a shift has occurred and it is now defined in legal terms as to what information a reasonable person would need to come to a decision. Some institutions go as far as requiring wording that people without secondary education (grade 8) would understand.

Other very interesting issues not covered here include but are not limited to the issues of implied consent, deferred consent and next-of-kin consent that can be extended to organ donation.

VI. Conclusion

The issue of informed consent for human experimentation has been discussed as an important part of biomedical research. Many issues within that of informed consent such as selecting the proper level of financial remuneration for participation and the assessment of mental competence are also valid and necessary topics for discussion in the context of biomedical engineering.

Informed consent is one of numerous topics addressed in the ethics course offered at the University of Ottawa and Carleton University [7]. Let's hope that the engineers of the future will have access to courses like this one and that cases of fraud and misconduct will become increasingly rare.

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Daphné Townsend obtained her undergraduate degree in electrical engineering at the University of Ottawa, Ottawa, ON and is now in her first year of a master's program in electrical engineering at the University of Ottawa and Carleton University. She started research for her thesis this summer under the supervision of Dr. Monique Frize of the University of Ottawa and Carleton University.

Address for correspondence: Daphné Townsend, B.a.Sc,
School of Information Technology and Engineering,
University of Ottawa, Ottawa, ON, Canada, K1N 6N6.
E-mail: daphne.townsend@gmail.com