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Dr. Foong to Chair University Committee

Dr. Choong Foong has assumed the Chair of the very important University committee which deals with ethics of laboratory animal experimentation. Dr Foong has been a member of the committee since January 1988. The committee deals with the protocols for animal experimentation. This is a very difficult time for those entrusted with the task of ensuring that all animal research complies with the very strict guide-lines laid down by the Medical Research Council. The animal rights groups in the Britain have recently made international news with the setting of a car bomb which injured a small child. The bomb was intended for a medical research scientist who was conducting research involving animals. This outrageous criminal action has caused considerable concern amongst the international medical research community. These are not easy times for the chair of our Dalhousie University Committee, a recent out break of hepatitis amongst the experimental mice has caused quite a problem. The busy schedule for the committee includes projected site visits to Sable Island to gain information on the research involving the seal population, as well as the Shubenacadie Wild Life Park. This is in addition to the visits to research Laboratories on Dalhousie Campus and some Hospital facilities.

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Research Theory

There could be no fairer destiny for any theory than it should point the way to a more comprehensive theory in which it lives on, as a limiting case.

Albert Einstein

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The Ethics of Research

All research conducted in our dental . faculty which involves human subjects has to be evaluated by the Ethics Committee. The ethical considerations of research have become much more important in the past 10 to 15 years. This has occurred in part due to the movement towards a more just and equitable society and an increase in the democratic freedom and equal rights. The concern for human rights and moral issues in clinical research has become a major factor. It has been said that benevolent paternalism was a dominant force in the early ethics of experimentation as well as in society in general in the early history of civilization. The consent to vivisection of criminals in the third century B.C. is an example of the ethics of human experimentation. A paternalistic attitude still persisted into modern times rooted in these historic attitudes. It was often ignorance of the powerless and poverty stricken which allowed the more affluent researcher considerable 'licence' to conduct unbelievable research experiments. Often such licence would be limited only by the researcher's conscience and the religious beliefs of the times. Ethics, in the early days of human experimentation, were often left to the individual judgment of the physician-researcher. Modern day researchers may be partly excused for yearning for the return of these bad old days as they painfully await the results of an "Ethics Committee" judgement prior to submitting their research grant application.

Biological and medical research in the late 1800's and early 1900's enjoyed a great deal of liberty and freedom as extensive experimental advances and developments of health care strengthened the justification and acceptance of limited ethical guidance. Whilst we may deplore these early experiments on human subjects, we also have to recognise that many of these early experiments, undertaken with minimal ethical guide-lines, have resulted in significant medical breakthroughs. One example is the discovery by Edward Jenner in 1796 of smallpox vaccination by inoculation of a healthy eight-year old boy. A further example, is yellow fever prevention which was significantly advanced by the deliberate infection of 'volunteers' in order to confirm disease transmission through bites.from mosquitos

A number of historical incidents and developments, have put the

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spotlight on human experimentation and sparked the public interest in medical research, which have resulted in a change in ethical considerations.

Individual freedom and respect for persons led historically to the development of the concept of autonomy. The origins of this philosophy, are rooted in ancient, medieval and modern history. For example the chronicle of Roman Law, the Institutes of Justinian, records "Freedom, from which we get the description of men as free, this is a man's natural capacity of doing what he pleases unless he is prevented by force or law..."The English Magna Carta of 1215, states: "No Freeman shall be taken or imprisoned or in any way destroyed.excepting by the legal Judgment of his peers, or by the laws of the land."

The French Revolution resulted in The Declaration of the Rights of Man and the Citizen. This states that "Liberty consists in the freedom to do everything which injures no one else." The specific elements of consent, so important now in ethics, flow in great part from this philosophy.

One of the major incidents which has focussed public concern on the application of these ethical principles in medical research was the shocking revelations at Nuremberg of the research atrocities conducted under Hitler on unwilling captives during World War ll. It was these revelations which led to the Nuremberg Code. The Code emphasizes respect for persons and the importance of voluntary informed consent.

However, having ethical codes and guide-lines is not sufficient. The need for surveillance in these matters is obvious from the fact that ethical guide-lines for experimentation existed in Germany well before the atrocities took place. These Guide-lines had been issued by the German Minister of the Interior in February 1931. Before we condemn these German atrocities let us recognise that many other unethical research examples are much closer to home.

In Canada, we have the case of Halushka v. The University of Saskatchewan, in which a university student was not told, in the course of his involvement in testing an anaesthetic, either that the drug was new or that a tube would be advanced through his veins to his heart. He claimed grave injury. In that case, Mr. Justice Hall stated: "There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice.

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The researcher does not have to balance the probable effect of lack of treatment against the risk involved in the treatment itself. The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent.

A major abuse of human ethics occurred in the United States with approval as late as 1969. The US Public Health Service Venereal Disease Division conducted a 40-year project on the effects of untreated syphilis in several hundred black men. Initially, no treatment was available, so there was no prejudice to them. However, even after the discovery of the effectiveness of penicillin, the study was continued and treatment was withheld. Experiments on senile patients in a hospital in Brooklyn, New York provide a further example which provoked public sensitivity, these unsuspecting individuals were injected with cancer cells.

Through these cases seem deplorable now, ethics are very much related to the times in which we live. It is clear that Jenner's experiments of 1796 could today only be conducted on a statistically significant sample of consenting subjects in an approved clinical trial. The practice of using teeth to be extracted for orthodontic reasons as experimental sites for *in vivo* testing of pulp reaction to dental restorative materials would perhaps not be allowed to-day as it was five or ten years ago.

In the face of an evolution of ethical values and the recognition of cases of abuse, public policy has now developed ethical codes and guide-lines to protect the subjects of research.

Following the Nuremberg Code, the Helsinki Declaration, was adopted by the World Medical Association in 1964. This was considerably modified in 1975, and now serves as a base for guide-lines for the ethics of research involving human subjects. In 1982, the World Health Organization and the Council for International Organizations of Medical Sciences produced "Proposed International Guide-lines" which address special needs encountered in research in developing countries. In Canada, the Medical Research Council has built upon this tradition and developed a set codes and guide-lines for the ethics of experimentation involving human subjects.

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Seven Year Total

The number of papers presented at the IADR and AADR meetings during the past seven years totals 16,012, the mean number of papers per meeting is 1,779.1 ± 380. The numbers range from as low as 1,168 for the 1986 IADR meeting in the Hague up to 2,361 for the 1988 IADR meeting in Montreal. If we look at the number of dental biomaterials papers presented during the past seven years we get a total of 2,652 papers with a mean of 294.7 ± 69.4 with a range from 190 at the 1989 Dublin meeting to 394 at the 1988 Montreal meeting. The dental materials papers expressed as a percentage of the total papers at the meetings has remained remarkably consistent being 16.5% ± 0.97. Ranging from 15% at the 1989 IADR Dublin meeting to 18.5% at the 1989 AADR San Francisco meeting. The coefficient of variation for the dental materials group share of the meetings is very low being only 5.9%. The IADR meeting in Dallas in 1984 had a total of 1,569 papers (15.3%, dental materials), whilst the 1988 IADR meeting in Montreal, the largest meeting to-date had a total of 2,361 (17%, dental materials). Comparing the 1984 Dallas to the 1988 Montreal meeting we see a 50% increase in total papers and a 64% increase in the number of dental materials papers. The regression plot of total Dental Materials Group (DMG) papers plotted against the total IADR/AADR papers during the period 1984-90 illustrates the remarkable consistency in the percentage of dental materials papers presented over 7 years.