MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

BWC/MSP/2005/MX/WP.2
9 June 2005

ENGLISH ONLY

Third Meeting
Geneva, 5-9 December 2005

Meeting of Experts
Geneva, 13-24 June 2005
Item 5 of the provisional agenda
Consideration of the content, promulgation, and adoption of codes of conduct for scientists

COMMON ELEMENTS OF CODES OF CONDUCT (I): CANADIAN GOVERNMENT CODES

Prepared by Canada

Introduction

1. Codes of Conduct in Canada are meant to reflect the value of research to advance knowledge, while always protecting the best interests of the general public. Norms for ethics are developed and refined within a constantly evolving societal context. This includes the need to continually advance the frontiers of research and for researchers to continually engage in increasing their knowledge, while at the same time maintaining their moral imperatives, ethical principles, and the law. While these are core principles that a given code of conduct should strive to address, it is nevertheless difficult to produce one code which will encompass all the various aspects that concern the different areas of biotechnology. To this end, rather than describing in detail the various codes of conduct in Canada, or trying to create a new all-purpose code of conduct, this paper, along with its two sister papers on association codes and academic codes, will examine some of the primary common elements from the various Canadian codes, as well as particularly innovative individual items, and put these forward as items that can be drawn upon to create a new, effective code(s) in the realm of government activities. While the background papers already prepared by the Secretariat have provided an overall insight on the broad subject of codes, the following paper will provide more in-depth information and cite specific examples of various governmental codes of conduct that are currently in effect in Canada.

Main Elements of the Government Codes

2. Governmental Codes are general in nature, but are meant to act as a guideline for requirements that are enacted throughout Canada. The following represent a selection of governmental life sciences codes in Canada. The main statements of each are as follows:

i The TriCouncil Policy statement: "Ethical Conduct for Research Involving Humans describes standards and procedures for governing research involving human subjects."

ii National Research Council: Adopted the Tri Council Policy Statement

iii Department of Research and Development Canada (DRDC) Human Research Ethic Committee (HREC): DRDC will provide a full or expedited review of all protocols submitted to it, in which human subjects participate in research projects, to ensure that all policies, consideration, standards, and safeguards as described, or intended by these guidelines are appropriately applies.

iv Canadian Institutes of Health Research (CIHR) - Has a duty to ensure that research carried out under its auspices involving humans or human biological material meets the highest ethical standards. Tri- Council Policy Statement applies to all research funded by CIHR.

3. The most important of the government codes, and the one that is often cited in other codes involving research on human subjects, is the TriCouncil Policy. The TriCouncil Policy is made up of three pre-existing organizations: Medical Research of Canada, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada. The Joint Policy was created to promote the ethical conduct of research involving human subjects. The Department of Research and Development Canada, which has used the TriCouncil policy as a guide in the creation of its own code of conduct, states:

> *"Direct experimentation will be confined to research projects that are necessary, scientifically sound, unlikely to be injurious to the subject, and where the benefit to be derived clearly justifies the risk incurred by the subject.*"

Common Elements of the Codes

4. The codes listed above all have somewhat different functions within the larger framework of government and the administration of behaviour. A basic tenant of all the codes is that there is a fundamental need for research, often involving human subjects. This research not only alleviates suffering (ie: by helping to find cures for disease) but it also expands the body of knowledge regarding human physiology (down to the micro level) and human behaviour, thus allowing for a better understanding and appreciation of all aspects of human existence. However, research of this nature can be misused or misdirected. In order to avoid this situation, there are several basic principles elaborated, in Canada's codes of conduct, that all scientists should adhere to when undertaking research on human beings.

Respect for Privacy and Confidentiality

5. Respect for privacy and confidentiality is meant to protect the access, control and the dissemination of personal information. This will set a standard to help protect the psychological integrity of the research subject. Just like a patient/doctor confidentiality agreement, this is meant to protect the personal information of the research subject, and to clearly indicate their rights in terms of the subject making informed decisions regarding what he/she thinks is appropriate.

Respect for human dignity

6. Humans are not meant to be treated and used in a research study as objects, or to be used solely as a means, even towards legitimate ends. Researchers must put the welfare of any person first in order not to degrade the research subject in any way. This is meant to protect any research subject from being used, or being put in a position that is potentially embarrassing and/or immoral without their knowledge and consent. This idea also serves to protect the research subject from being subjected to excessive tests that may put them under too much emotional and/or physical stress.

Balancing harms and benefits (minimal risk)

7. This is critical to the ethics of human research. The benefits of a research study must always be weighed against the risks. This is simply a balancing act, the harm to a research subject (psychological and physical) should never outweigh the benefits (cures for diseases, inoculations, etc) even if the research is being done to benefit a larger population.

Minimizing harm

8. Minimizing harm is the duty to avoid, prevent, or minimize harm to others. The research subject is not to be subjected to unnecessary risks, and is only to be exposed to the least amount of scientific tests that will ensure the generation of valid data.

Maximizing Benefits

9. Maximizing Benefits is intended to produce the maximum benefits for both the research subjects themselves, as well as for society as a whole.

Respect for free and informed consent

10. The potential research subject should be well informed about the research that will be taking place before consenting. All the information should be given in a comprehensible written and verbal form. The research subject should not be coerced (including by utilization of either monetary or emotional incentives) into agreeing to participate in the research. The research subject should at all times feel safe and comfortable when giving his/her consent.

Respect for Vulnerable persons

11. The interests, rights, and welfare of those who are incapacitated, mentally challenged, or who have health risks must be protected. Those who cannot give informed consent themselves will need a third party to give consent. The third party should not be manipulated in any way to force them to agree to a study that will harm or permanently scar the vulnerable person. An incapacitated or mentally challenged person should not be treated with the utmost respect in the course of a research study.

Conflict of Interest

12. Researchers, research subjects, institutions, and professional bodies hold an interdependent trust relationship. This relationship can be put at risk by conflicts of interest that may compromise independence, objectivity or ethical duties of loyalty. As an example, a scientist cannot submit a research study to a Research Ethics Board that he/she physically sits on as a member.

Further Points of Interest

13. There are a number of other items raised in the various governmental codes of conduct that, while not necessarily common to all the codes, are nevertheless useful and valuable ideas. Some of these are as follows:

i Ethical Committees: The composition and procedures of any ethical committee or review board is very important to its overall efficiency and effectiveness. A particularly good example with regard to the composition of a committee would be that of the DRDC HREC. The DRDC-HREC standing committee is comprised of various individuals with particular specialities including members versed in medicine, physiology, psychology law, and ethics as well as an individual external to the organization. It is also important to note that a psychologist on hand is very important when dealing with research subjects, and analyzing the possible outcomes of a proposed research project. This is the only committee member that would have the expertise to identify if there will be any ill psychological effects on the human subject.

ii Lack of Consensus on an Ethics Board: Ethics boards are comprised of individuals who will often have differing views, particularly with regards to research in "morally grey" areas. While every effort is made to achieve consensus, in some cases this is not possible. As a way of resolving these potential conflicts, the TriCouncil Policy states that when a Research Ethics Board (REB) receives a potential research project, the committee must try to come to a consensus. In the case of this not occurring, those members who have dissented from the majority view must inform the researcher of their concerns. Following the publication of an REB's decision, the researcher has the right to request reconsideration. If during a reconsideration review there is again a deadlock in a decision, an independent appeal board will be brought into review the case and make its own recommendations.

iii Research Outside of Canada: In the case of a Canadian scientist undertaking research outside of Canada but who represents specific Canadian interests (be they commercial, academic or governmental), the TriCouncil Policy states that ethical review of the research is still required. The theory is that an institution is responsible for the ethical conduct of research undertaken by its faculty regardless of their location. Rules pertaining to research abroad are interpreted according to the agreed upon Helsinki Accords. Researchers will be obliged to respect the laws and customs of the countries in which they are working. However, a Canadian REB will not necessarily withhold permission for a Canadian research project in another country to proceed based solely on the fact that governmental authorization has been delayed, or the government has expressed a dislike of a particular individual researcher, unless legitimate grounds for disallowing the research can be demonstrated.

iv Controversial Research: In some instances, legitimate research may be viewed as being particularly controversial, either due to ethical, dual use or other practical considerations. In such cases, a system for minimizing the impact and perception of the controversy is important. A good example of this is CIHR sponsored research that aims to conduct studies from recovered umbilical cord and placenta tissues. In the case of this type of research, there must be free and informed consent from the parents (or only the mother if the father is no longer involved in the relationship). If there is any disagreement between the parents they are rejected as potential donors. This type of consent should also be used with regard to research subjects who are mentally incapacitated and cannot make their own decisions. In such cases, it is preferable to have more than one person making medical decisions on their behalf. It is important to note that this sort of "double-check" is useful not only in matters of tissue donation, but also with regard to other ethical issues that surround potentially controversial research.

Conclusions

14. Codes of conduct are not meant to be one-size fits all solutions. Different research situations and settings may require different approaches, which have to be reflected in these documents. Nevertheless, there are certain common elements that codes can contain in order to provide a broad basis for common understanding and practice. This paper has highlighted these aspects in governmental codes, but some basic similarities can also be found with the elements elaborated in the papers on associational and academic codes. The different codes in Canada have served researchers well in that they provide unique guidance while still retaining the broad elements that link them together and provide a connection to the broader legislative framework in existence in Canada. While not exhaustive, it is hoped that this description of the common elements of the governmental codes in Canada will provide some food for thought to those States Parties looking to develop similar documents. Codes are living documents, and thus function best when they are constantly being refreshed and updated with new ideas, interpretations and concepts. As such, Canada would welcome thoughts from States Parties regarding other elements or refinements that could be added to this study.

———