

Learning to Conduct Ethical Research in Humans: Educational Needs and Models

Forum for Institutional Review Boards (IRBs)/Research Ethics Boards (REBs) in
Canada and the United States (FOCUS)



developed within the
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FOCUS

**An International Conference on
Learning to Conduct Ethical Research in
Humans: Educational Needs and Models**

Forum for IRBs/REBs in Canada and the United States (FOCUS)

*Wishes to thank its generous
contributors and partners*

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Special Programme for Research & Training in Tropical Diseases (TDR)

Department of Health and Human Services (DHHS)

Health Canada (HC)

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Acronyms

AAMC	Association of American Medical Colleges
ACGME	Accreditation Council for Graduate Medical Education
BSS	Behavioural and Social Sciences
CGS	The Council of Graduate Schools
CIHR	Canadian Institutes of Health Research
FOCUS	Forum for Institutional Review Boards (IRBs)/Research Ethics Boards (REBs) in Canada and the United States
HRPPP	Human Research Participant Protection Program
IOM	Institute of Medicine
IRB	Institutional Review Board
LCME	Liaison Committee on Medical Education
MRC	Medical Research Council
MSOP	Medical School Objectives Project
NCEHR	National Council on Ethics in Human Research
NIH	National Institutes of Health
NSERC	Natural Sciences and Engineering Research Council of Canada
OHRP	Office for Human Research Protections
ORI	Office of Research Integrity
PRE	Interagency Advisory Panel on Research Ethics
REB	Research Ethics Board
RCR	Responsible Conduct of Research
RCREC	Responsible Conduct of Research Consortium
SSHRC	Social Sciences and Humanities Research Council of Canada
TCPS	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
TDR	Tropical Diseases Research
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Organization

Executive Summary

The Forum for Institutional Review Boards (IRBs) / Research Ethics Boards (REBs) in Canada and the United States (FOCUS) grew out of a World Health Organization (WHO) initiative and has, as a major objective, the development of capacity building in the ethical review of human research.

The topic of the fourth¹ international FOCUS conference held in Washington DC, USA (June 1-2, 2006) was “Learning to Conduct Ethical Research in Humans: Educational Needs and Models.” Sixteen presentations and multiple sessions for questions, comments and discussions took place over two days (refer to Appendix A for the conference program). This report summarizes the outcomes of that conference and includes references to relevant literature.

The principle theme of the FOCUS conference was university-based education and training in the ethical conduct of research for new investigators. Other themes included the need for *ongoing* education and training in research ethics, as well as the way in which education and training in research ethics can be conceptualized as part of the larger topic of *responsible conduct of research* (RCR). It became clear that education needs to go beyond new investigators to target experienced investigators and research team members, members of Research Ethics Boards (REBs) and Institutional Review Boards (IRBs), and others.

The recommendations that emerged from the discussions of learning to conduct ethical research in humans fall into five main categories:

1. **Setting the Agenda for Education in Research Ethics:** Education in research ethics must be an integral part of the curriculum of every discipline that engages in research and it can be conceptualized as part of a greater commitment to the Responsible Conduct of Research. One way to support learning to conduct ethical research in humans would be an institute requirement that [at least] 0.1% of every research budget be directed towards education and training in research ethics and promoting RCR.
2. **Targets of Research Ethics Education:** Education in research ethics should target graduate and medical students (even those not planning to become investigators should still be able to understand and evaluate research), investigators at all levels and every member of the research team, those who might be mentors or role models to new investigators, members of IRBs/REBs, administrators and those who write research ethics guidelines and administer grants, as well as communities that want to develop their capacity to participate in research.
3. **Approaches to Learning Research Ethics:** Learning about research ethics has to occur in many different modes and styles, with the guidance of people who believe in the importance of research ethics education.
4. **The Content of Education in Research Ethics:** Education and training in research ethics should be largely discipline-specific, and designed to provide learners with both knowledge and skills. The curricula should be broad enough to include important RCR topics such as authorship and transparency in data collection, and flexible enough to incorporate knowledge gained from incidents of misconduct.

¹ Reports summarizing the outcomes of previous FOCUS conferences are available online:
<http://www.ncehr-cnerh.org/english/international/focus/publications.php>

5. **Engaging the Academic Community:** There are opportunities for investigators interested in research ethics to contribute to a greater understanding of the issues involved. For example, the analyses of data regarding decisions made by IRBs/REBs, and their impact on the ethical conduct of research, could contribute to curricula in research ethics. The evaluation of different approaches to education in research ethics is also an area of vital importance.

To be able to conduct research on humans is both a privilege for investigators and a boon to the people who will ultimately benefit from the information acquired through such scientific enquiry. While we are accustomed to the notion that investigators need education and training in order to be able to acquire the knowledge and use the skills necessary to conduct excellent research, we are less familiar with the idea that learning to conduct research in an *ethical* manner is also a necessary part of that education.

While there are few studies to suggest whether or not research ethics education can reduce the frequency and seriousness of incidents of scientific misconduct, it is generally expected that education – along with appropriate guidance and regulation – will have a beneficial effect on the way scientists operate in the 21st century. Leadership in this endeavour must come from universities and other educational institutions, professional standard setting and credentialing organisations, research funding agencies and discipline-specific societies.

1.0 Conference Details

1.1 Conference Description

The Forum for IRBs/REBs in Canada & the United States (FOCUS) is one of five regional fora established as part of an initiative that began with the Special Program for Research and Training in Tropical Diseases (TDR) of the World Health Organization (WHO). A major objective is to assist in the worldwide need for capacity building in the ethical review of biomedical research. Activities of the fora include regional workshops.

FOCUS identified a list of conference topics of mutual interest to those concerned with the ethical review of research in humans in Canada and the United States. The topic of educational needs and models relating to the ethical conduct of research with humans was acknowledged as a major area of concern and it became the subject of the fourth international FOCUS conference. Key organizations in Canada and the United States were invited to send participants.

1.2 Conference Objectives

- Identify best practices in human research ethics education in Canada and the United States.
- Provide an opportunity for networking and future collaboration at national, international and interdisciplinary levels.

1.3 Conference Outcomes

- Improved understanding of needs, models and other issues in human research ethics education.
- Improved understanding of similarities and differences in dealing with these issues at local and national levels as a basis for future action.
- Appropriate distribution of the proceedings and recommendations of the conference.

2.0 Overview of Human Research Ethics Education

2.1 Themes of This Report

The principle theme of the FOCUS conference and this report is education and training for investigators and research staff. When it comes to the protection of human research participants, the people who have the most contact with participants and who are, therefore, the most in need of such education and training are the members of the research team. The conference focused on education and training at the university level and specifically for *new* investigators. That emphasis is particularly important because education designed to ensure investigator competence does not necessarily include a research ethics component.

A secondary theme concerns *ongoing* education and training in research ethics, as well as education for the experienced investigator and research team member, members of Research Ethics Boards (REBs) and Institutional Review Boards (IRBs), and others.

A third theme that emerged from the conference is the way in which education and training in research ethics can be conceptualized as part of a larger topic; that is, *responsible conduct of research* (RCR).

Education versus Training

According to one definition, education and training may be seen as “opposing terms, the former broad, knowledge-based and general, the latter narrow, skill-based and specific” (Tight, 2003). However, UNESCO (United Nations Educational, Scientific and Cultural Organization) suggests that whatever the name given to the activity, education is understood to involve “organized and sustained communication designed to bring about learning” which is defined as “any improvement in behaviour, information, knowledge, understanding, attitude, values or skills” (1997). For the purpose of this report, therefore, all knowledge transfer activities will generally be known as “education.”

2.2 The Goals of Education in Research Ethics

The need for education in research ethics is underscored by publicity regarding the perils of participating in research due to mistakes or intended violations of research ethics on the part of investigators (e.g., Munro, 2004). Many believe that the best way to improve the ethical practice of research is through education.

Some of the goals of education in research ethics are:

- Prevent misconduct in research.
- Protect research participants.
- Protect society against erroneous conclusions drawn from flawed research.
- Develop trustworthy researchers who will conduct research that is both scientifically meritorious and ethically sound.
- Create an enthusiasm for research, particularly among those who are trained primarily to practise medicine.
- Circumvent misunderstandings and disputes; for example, increased numbers of collaborations are leading to more problems with attributing authorship (Wilcox, 1998).
- Increase awareness in those who conduct research about their responsibilities. If they understand how important it is to conduct ethical research they will be better scientists and less willing to overlook transgressions (becoming whistleblowers when necessary).
- Improve the public’s confidence or trust in research. This is not just for the sake of good public relations but because researchers are part of and, therefore, owe an obligation to the community. It is also important to remember that it is a privilege to conduct research, not a right.

2.3 The Focus of Education in Research Ethics

Ethics is an integral part of the practice of any discipline that conducts research; it is not something that is simply added at the end, or the route to getting a consent form approved by the IRB/REB.

The focus of research ethics education for investigators should incorporate the following:

- Start with education in professional standards such as data management, rules of authorship, and the protection of human participants. This could be part of professional development, and the

- effectiveness of such courses could be assessed by objective testing.
- Go beyond regulations and guidelines and stress the ethical underpinnings for appropriate research conduct. (Some believe that it is unnecessary to include the principles of ethics or ethical decision-making in such education but there is no evidence that training in professional standards is sufficient to change the behaviour and attitudes of students.)
 - Provide the tools to engage in ethical decision-making during research. Graduate and medical school students are well trained in critical thinking and decision-making but they may need direction when applying those skills to ethical issues. Students need to practise their ethical decision-making skills in the context of research issues.
 - Stress a commitment to being accountable (which includes practical training in methods of assuring transparency in data collection).
 - Include training in the best ways to communicate so that stakeholders with different priorities in the enterprise of research (e.g., investigators, research administrators and IRB/REB members) understand what is important to their colleagues.
 - Nurture an understanding in all investigators of the ethical issues posed by their research which need to be addressed by IRBs/REBs.
 - Train physicians to identify ethics issues with multi-centered/pre-packaged trials.
 - Create a distinction between innovation (e.g., in surgery) and research. Research is generally defined in terms of strict criteria and well defined endpoints. Medical innovation may sometimes seem experimental in nature but is not necessarily research in the formal sense. [See McKneally and Daar (2003) for a description of an ethical paradigm that encompasses the concept of innovation.]
 - It may be helpful to offer ethics education in more than one language, depending on the community involved. For example, while linguistic duality is a recognized feature of life in Canada (i.e., French and English), there may be Aboriginal communities involved in research (i.e., providing participants and members of the research team) who would benefit from instruction in their own language. In the U.S. there are Spanish-speaking communities similarly involved in research. Project TRES (Training in Research Ethics and Standards)² from the San Diego State University is a culturally tailored, content-appropriate, Spanish-translated research ethics curriculum.

Given that anyone is capable of making a mistake – investigators, IRB/REB members, administrators – it is important to keep track of these errors and use them for educational purposes. Both the violations of research ethics and the range of possible solutions will be important topics for students.

Research has identified some of the motives that scientists have for wrong-doing (e.g., believing that the system is not “fair” in terms of receiving grants, tenure, promotion, etc.) which, in turn, may lead to encouraging the attitude that breaking rules is acceptable. Offering education about the reward system in academia can address the perception of injustice held by many researchers. Such education can be explicitly connected to questions of procedural justice covered in courses that examine the system from the viewpoint of ethical principles.

The ultimate goal of education in research ethics is to instil a sense of what is right and what is wrong within the research enterprise. It should also foster a commitment to be honest, accountable, objective and efficient.

² Project TRES: <http://projecttres.org/>

2.4 How Does Education in Research Ethics Fit into the Responsible Conduct of Research?

From the perspective of IRBs/REBs, the primary goals of teaching ethical research behaviour have to do with the protection of human participants and society at large. There are other parties to the enterprise of research with the potential to be harmed by unethical behaviour: students (failing to be given credit for authorship), scientists (being the target of plagiarism), and science as a whole (falsification of data that leads to a lack of trust by the public). If one takes a larger view of the need to champion integrity in research for the benefit of all, then it makes sense to think of RCR education rather than the subset of the topic that is commonly known as “research ethics.”

According to the Responsible Conduct of Research Consortium (RCREC),³ RCR education should be designed with two primary outcomes in mind: knowledge and skills. The list of suggested topics taken from RCREC is not intended to be comprehensive but it does cover the principal areas usually included in RCR curricula.

Knowledge:

- Responsible Conduct
- Ethics and Morality
- Data Management [incl. transparency]
- Animal Subjects
- Human Participants
- Conflicts of Interest
- Publication
- Authorship
- Peer Review
- Collaboration
- Mentoring
- Research Misconduct
- Whistle blowing

Skills:

- Ethical Reasoning
- Critical Thinking
- Conflict Resolution
- Arbitration
- Mediation
- People Management
- Time and Stress Management

One more item can be added to the list of necessary RCR topics: instructing scientists in ways of fulfilling their responsibility to step outside of the academic community and deal with the public, often through the media, in order to make clear how science operates, what we know, and what we do not know. In this way the academic community can take part in the public debate that is often stimulated by matters of science and research.

2.5 Ways to Promote Education in the Responsible Conduct of Research

The Office of Research Integrity (ORI) promotes integrity in biomedical and behavioural research supported by the U.S. Public Health Service⁴. Recently the ORI has ventured beyond its primary function of policing research misconduct to supporting research in education and research integrity. It has identified a number of opportunities that exist within colleges, universities, medical schools, and research institutes to promote education in the responsible conduct of research through activities that already occur on a routine basis. For example:

³ The RCREC Website (<http://rcrec.org/r/index.php>) offers excellent resources for teaching RCR. It is sponsored by the Research Ethics Program, University of California, San Diego.

⁴ Office of Research Integrity: <http://ori.dhhs.gov/>

- Research methods courses
- Departmental faculty meetings
- Training sessions offered by IRBs/REBs, Institutional Animal Care and Use Committees, and Institutional Biosafety Committees
- Experiential research programs for graduate and undergraduate students
- Orientation sessions for new faculty, post-doctoral fellows, graduate students, and graduate assistants
- Training sessions for new department chairs
- Meetings or luncheons for new faculty hosted by university officials
- Departmental activities such as dissertation groups, seminar series, journal clubs
- Institution-wide lecture or discussion series
- Professional development programming offered by the graduate school
- Activities sponsored by graduate student and post-doctoral organizations
- Feature articles on RCR issues in the campus newspaper and organizational websites
- Collaboration with graduate program coordinators to promote RCR training
- Communications between the chief research officer and the campus community

According to the Poynter Center for the Study of Ethics and American Institutions at the University of Indiana (see Appendix C) many members of science faculties would be willing to include research ethics in their curricula but lack training in teaching ethics themselves. There are a number of resources⁵ to assist those who would like to include aspects of research ethics in their courses, or who would like to strengthen their ability to mentor students in issues surrounding research ethics (see Appendices B & C for examples of ethics organizations and online courses). The Poynter Center also offers an annual three-day workshop on Teaching Research Ethics. Topics include an overview of ethical theory and many substantive research issues (e.g., conflicts of interest, using humans in clinical and non-clinical research, and responsible data management) as well as techniques for teaching in this area.

Promotion of education in research ethics to investigators can also be couched in the form of an academic challenge. Questions or controversies that come up in the ethics review system are opportunities for empirical evaluation that can produce data to inform IRB/REB decisions as well as contribute to educational curricula. This could be an opportunity for collaboration between those who can identify the problems and those with the skills to assess the solutions.

2.6 Challenges to Education in Research Ethics

Many investigators assume that they do not need education specifically in research ethics because they have already learned how to conduct research within their own discipline. Of course, twenty-five years ago physicians said there were no ethical issues in clinical medicine, just medical ones. Now medical ethics is an important part of their training. The same evolution should occur in research ethics.

Specific challenges to education in research ethics include:

- Research ethics is often seen as an entirely bureaucratic exercise; something that is added on after the project is designed.
- Particularly in the natural sciences and increasingly in some branches of the social sciences, there is an intensively competitive atmosphere which may produce researchers who are willing to cut ethical corners for their professional survival.

⁵ Poynter Center Resources for Teaching Research Ethics: <http://poynter.indiana.edu/tre/resources.html>

- It is easier to convince students of the importance of the protection of human participants when the research is biomedical as opposed to BSS. The potential risks associated with BSS research have not been clearly delineated.
- In BSS research it is often difficult to see how traditional notions of research ethics can apply. Sometimes the more a participant is informed (as normally required by the concept of informed consent), the less effective the research. This is often perceived by the BSS research community as the imposition of biomedical standards on non-biomedical investigations.
- There is an attitude within some universities and faculty associations that “external” research ethics requirements are somewhat “paternalistic” in that they usurp the right of independent investigators to make their own decisions about what they need to know. Academics often feel well qualified to conduct research because of the knowledge acquired within their own discipline. In Canada, for example, universities usually require compliance with the *Tri-Council Policy Statement (TCPS)* but do not specify the educational route to reach that goal.
- There is less discussion and, therefore, education about authorship, conflict of interest, rigour of design and a number of other important issues that make up RCR.
- There is often ignorance of ethical codes.
- Mentors may not be adequately trained in issues of research ethics and supervision of students may be inadequate. Students are often used to learning through observation so without appropriate guidance, or because of inappropriate role-modelling, they may pick up flawed habits. Also, students exposed to ethically questionable practices (e.g., not given appropriate credit on publications) come to think of it as the norm.
- Pre-packaged clinical trials from pharmaceutical companies do not necessarily allow clinicians to put their ethics education to practical use.
- Students already face a crowded curriculum that creates pressure to minimize or omit teaching in research ethics.

There are some highly regarded online courses in research ethics (e.g., the CITI Course in the Protection of Human Research Subjects, see Appendix C) but they also raise concerns about the potential misuse of the system. It is possible to re-take the quizzes until users achieve a passing score, and it is also possible that users will share test answers instead of learning directly from the course material. The irony here is that teaching integrity can be in question because of the possible lack of integrity of the users.

Another concern with courses such as CITI is that institutions can pick and choose the modules they deem important for their investigators, even within the biomedical and behavioural research streams. This means that there may be discrepancies in the type of knowledge acquired by different users of the CITI tutorial. On the other hand, being able to tailor the education to the needs of the institution and its personnel can also be seen as a strength of this pedagogical approach.

2.7 Who is the Target of Education in Research Ethics?

In most institutions, research ethics education comes in the form of individual courses offered by particular departments for their students. It is rarely identified as something that is important on an institution-wide level for everyone who might be part of that facility.

In the United States, or anywhere that NIH-sponsored studies are conducted, research ethics education is largely tied to NIH grants. The NIH requires each institution to certify that key personnel on a grant are trained.

National Research Service Awards (NRSA) come in the form of individual fellowships or training grants for departments/programs to support pre and post-doctoral training of students who undertake biomedical,

behavioural, or clinical research. NRSA policy⁶ requires students to obtain instruction in RCR; however; there are no specific curricula offered (“Policies for the Use of Human Subjects” is just one of the suggested topics). Students may participate in formal and/or informal activities such as courses (credit or non-credit), seminars or discussion groups. There are vast differences in the type(s) of training received by students at different institutions. Also, there are within-institution differences in quantity and quality of research ethics education acquired by students, depending on whether or not they are funded by NRSA.

It has also been pointed out that students do not necessarily find ethics education particularly interesting or credible, particularly for those coming from the perspective of the “hard” sciences. At the same time, for some students even one course in research ethics can stimulate a greater awareness of the issues, and a desire to pursue the topic in greater details (Anestidou, 2002).

In Canada, the three major funding agencies encourage institutions receiving money to provide education in research integrity to all those who are involved in the collection, recording, citing, reporting and retention of scientific or scholarly material (CIHR, NSERC & SSHRC, 1994).

Although graduate and medical students may be the primary target of education in research ethics and RCR they are only part of the research landscape. To have a broader effect, education concerning the ethical conduct of research with humans should be targeted at researchers at all stages of their career (Heitman *et al.*, 2005). There may also be a need to offer training to mentors, which would include institutional expectations for this role. As well, lay research staff may require a basic foundation regarding research; for example, the tendency for some participants to subscribe to the *therapeutic misconception* in which they confuse the goals of research with their treatment (Lidz, 2006). Even educating those people who administer awards or provide grants might be beneficial. [It has even been suggested that the target of education should be participants so that they can better represent their own interests rather than relying on scientists.]

2.8 Violations of Research Ethics

Several recent articles have stimulated much interest and concern about research misconduct (De Vries *et al.*, 2006; Martinson *et al.*, 2005; Martinson *et al.*, 2006). Scandals surrounding prominent scientists contribute to the declining confidence of science in the United States and elsewhere. The way in which the media report such problems can impact upon research not directly linked to the scandal (Seale *et al.*, 2005).

Scientists often say that they can police themselves but the peer review system - the self-correcting, self-policing system of science - is not the main source of exposure of research misconduct; violations are almost always exposed by whistleblowers.

When attempting to describe the extent of research misconduct it is important to take into account dimensions such as seriousness, frequency and potential for harm; otherwise, pooled data concerning misconduct may be misleading. At the same time it is important to keep in mind that even seemingly “benign” forms of misconduct such as sloppiness, as opposed to intent to fabricate, can result in extremely serious consequences. [See Crewdson’s book describing the confusion around the discovery of the AIDS virus (2002).] Furthermore, while self-report may grossly underestimate the incidence of misconduct, reports of *observed* violations may suffer from overlap that can result in inflated assessments of problems.

A study, based on 4,000 responses from early and mid-career scientists, reported that 33% of the sample

⁶ For NRSA policy see: http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part10.htm#_Toc54600187.

said that they had engaged in at least one of the ten sanctionable behaviours named (Martinson *et al.*, 2005). Some have suggested that the Martinson study offers an overly simplistic analysis of the complexities involved in the behaviour of scientists; however, it should be noted that Martinson’s goal was not to establish prevalence but to get scientists to react to certain issues identified in focus groups.

Students caught plagiarizing or “cooking” data will often say that they were never taught the rules of citation or data management. What they typically mean, however, is that they were never taught the seriousness of plagiarizing or data manipulation, or their associated penalties. There is also great potential to stunt the ethical awareness and growth of students through poor mentorship, whether blatantly unethical or simply neglectful.

Instead of focusing on research misconduct, some argue that we should be more concerned about accountability. Investigators should be held accountable for the accuracy and objectivity of the research record, and the efficient use of research funds for public health, public welfare and public safety. There is need for well-conceived policy that would encourage the creation of clear and comprehensive guidelines, enhanced quality control, more careful grant review, an improved system of reporting of problems, and better supervision, mentoring and training for students.

A demand for more rules and regulations regarding the conduct of science is often the first reaction to reports of research misconduct. Many, however, including the Council of Graduate Schools (CGS) suggest that the most effective way to reduce wrongdoing in science is not through more government regulation or self-policing but by education.

Defining Research Misconduct

In order to gauge research misconduct one has to relate it to a particular definition; however, this has often been difficult to accomplish. Recent U.S. Federal policy defines research misconduct as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results” (CFR Title 42, Part 93, 2005). In Canada, however, the funding agencies [i.e. CIHR, NSERC & SSHRC] have taken a slightly different approach by regarding “any action that is inconsistent with *integrity* as misconduct” (1994). Integrity is defined in terms of certain principles, and institutions are encouraged to use these principles when developing research policy (CIHR, NSERC & SSHRC, 1994). Research Institutions, on the other hand, generally use a broader definition that includes items such as financial mismanagement. De Vries *et al.* (2006) suggest that researchers tend to associate the term “misconduct” with more mundane, everyday problems. They group these everyday problems into four categories: the meaning of data, the rules of science, life with colleagues, and the pressures of production in science.

3.0 Research Ethics Education for Physicians

Historically, physicians engaging in research have learned through the apprenticeship model. There was very little formal education so medical students looked to mentors in order to learn how to conduct clinical research. The field has become much more complicated and the “see-one, do-one, teach-one” approach is no longer adequate.

The Liaison Committee on Medical Education (LCME)⁷ is the nationally recognized accrediting authority for medical education programs leading to the M.D. degree in Canadian and American medical schools. According to LCME standards (2006), a medical school must teach medical ethics; however, no specific mention is made of the ethics of conducting research.

3.1 The Canadian Experience

In Canada there is no national requirement for research ethics education. The field of research, however, is changing in two ways: research training is now often formalized (e.g. in MSc & PhD programmes), and there are more rigorous standards for publication (including the requirement for IRB/REB approval of studies).

The Royal College of Physicians and Surgeons of Canada (RCPSC)⁸ has taken a leadership role in the area of research ethics. In 2003, the RCPSC Task Force on Clinical Research made specific recommendations concerning education in research ethics for students and practising physicians. The organization has been progressive in terms of putting in place a bioethics curriculum; there are cases and structured analyses that exist primarily in the areas of medicine, surgery, ob-gyn, psychiatry and paediatrics. These courses are available online, and are used primarily by those in training even though they are also available for those in practice and can be the focus for education in clinical research ethics.

The equivalent of RCPSC for family practice in Canada is the College of Family Physicians.⁹ This organization pays some attention to research ethics but, in general, most of the ethics referred to in educational material are concerned with practice.

There are several examples of Canadian programs aimed at physicians wishing to acquire education in becoming clinician researchers:

1. The Royal College Clinician Investigator Program (CIP)¹⁰ is an accredited postgraduate medical education training program of RCPSC which prepares individuals for a career combining specialty medical practice and research. This program has ties to the Joint Centre for Bioethics, which is dedicated to providing leadership in bioethics research, education, and clinical activities. There are rigorous expectations of individuals who are training in conjunction with their specialty training in clinical research.
2. McMaster University has a Graduate Program in Health Research Methodology¹¹ which educates health professionals and others in population health, clinical epidemiology, health care and health services research methods (offered at the master's level and the doctoral level). One of the strengths of that program has been the requirement for students to prepare properly-designed research protocols. Students are now expected to submit their research protocols to an ethics review; this is a good way to provide an early appreciation of the practical side of research ethics.

⁷ The LCME is sponsored by the Association of American Medical Colleges and the American Medical Association: <http://www.lcme.org/>

⁸ The Royal College of Physicians and Surgeons of Canada oversees the medical education of specialists in Canada: http://rcpsc.medical.org/main_e.php

⁹ The College of Family Physicians of Canada is a national voluntary organization of family physicians that makes continuing medical education of its members mandatory: <http://www.cfpc.ca/English/cfpc/home/default.asp?s=1>

¹⁰ The Royal College Clinician Investigator Program at the University of Toronto's Faculty of Medicine: <http://www.utoronto.ca/cip/about.html>

¹¹ McMaster University Health Research Methodology Program: <http://www.fhs.mcmaster.ca/grad/hrm/index.htm>

3. The Division of Experimental Medicine at McGill University¹² offers a graduate diploma in Clinical Research that introduces participants to the issues involved in clinical research from the initiation of protocols to data analysis. It is open to medical professionals (both in academia and industry) having an undergraduate degree in the medical/allied sciences.
4. On August 21, 2006 the University of British Columbia implemented a new online system for applying and managing research applications. Researcher Information Services (RISe)¹³ provides “just in time education” for applicants. In the process of completing an application there is an almost painless and requisite educational experience.
5. GEREQ (see Appendix B) was an educational initiative that had a large number of modules concerned with medical research education (N.B. the project has come to an end). It focused on the protection of human participants and also on broader issues of research ethics.

Of course, education in research ethics is not just for researchers. For example, medical students at the University of Toronto are taught about research ethics through four mechanisms:

1. A lecture which covers areas such as the TCPS.
2. Second year students are required to put together a research project in their community health course and then to submit it and have it approved by the IRB/REB.
3. There is a small module on consent in the surgery rotation.
4. Research Ethics Day is a one-day session where the residents who are in the laboratory (this includes health policy or education as well as bench) and graduate students from the Joint Centre for Bioethics (<http://www.utoronto.ca/jcb/home/main.htm>) put on sessions about ethical issues such as authorship or dealing with the commercialization of university science. It is a very well-received method of teaching research ethics.

3.2 The American Experience

In 1998, the Association of American Medical Colleges established a task force to examine ways to mitigate the shortage of clinical and translational investigators, as well as address the current state of clinical research education in medical schools (AAMC, 2000). The Task Force made three recommendations in the area of education:

1. Medical schools and teaching hospitals should develop a *culture of support* around clinical research that would transmit the excitement of research to medical students, residents and fellows.
2. Clinical research training programs should define a rigorous set of competencies, skills and knowledge-based requirements.
3. Medical schools and teaching hospitals should develop model training programs and credentialing for clinicians who wish to participate in clinical trials.

In 2002, the Institute of Medicine (IOM)¹⁴ recommended that “integrity in research” should be developed in the context of an overall research education program. Their report suggested that “Education in the responsible conduct of research is critical, but if not done appropriately and in a creative way, then education is likely to be of only modest help and may be ineffective” (IOM, 2002).

¹² McGill University Division of Experimental Medicine: <http://www.medicine.mcgill.ca/expmed/default.htm>

¹³ UBC Researcher Information Services: <http://www.orsil.ubc.ca/ethics/clinical/c-rise.htm>

¹⁴ The IOM is a non-profit organization that provides science-based advice on matters of biomedical science, medicine, and health. See: <http://www.iom.edu/>

The Medical School Objectives Project (MSOP) is an initiative designed to reach general consensus within the medical education community on the skills, attitudes, and knowledge that graduating medical students should possess (see: <http://www.aamc.org/meded/msop/start.htm>).

It is important to expose medical students to clinical research without necessarily expecting that they become researchers. Students should be able to read and understand their own literature and be able to translate it into lay language for patients. There is also a need to teach ethical sensitivity (e.g., awareness of conflicts of interest, or the existence of the therapeutic misconception) so that students can appreciate the role and potential impact of clinical research in the care of patients.

A second AAMC Task Force (2006) recently concluded that slightly more than half of medical schools had enhanced their ethics curriculum since the first report. However, the ultimate conclusion was that while there are many opportunities for education in clinical research, there are few requirements. This Task Force made specific recommendations with measurable objectives, including:

Recommendation 1: Every future physician should receive a thorough education in the basic principles of translational and clinical research, both in medical school and during residency training. It has been estimated that approximately 80 percent of clinical trials are conducted outside of medical institution; therefore, it is important to make sure that clinicians conducting research without the institutional umbrella of a “human research participant protection program” (HRPPP) are well versed in ethical issues.

Recommendation 2: The LCME should add education in translational and clinical research to the requirements for medical school accreditation, and the Accreditation Council for Graduate Medical Education (ACGME) should embed understanding of translational and clinical research within its required core competencies.

Recommendation 3: Training in translational and clinical research should be accelerated through comprehensive re-structuring so that these scientists can become independent clinicians and investigators at the earliest possible time. The average age of first time recipients of NIH grant is increasing; if we want more physicians conducting good, hypothesis-driven research (not just clinical trials), it will be important to find a way to accelerate competency to apply for grants.

Recommendation 4: HRPPPs should be made more effective and efficient by (a) trans-agency harmonization of federal regulations e.g., NIH and FDA as called for many years ago by then-Secretary of Health and Human Services Donna Shalala, (b) accreditation of HRPPPs, (c) simplification of institutional regulatory compliance processes, and (d) expanded use of central IRBs in multi-site research.

One example of an approach to research ethics education exists at the University of Washington, where all researchers are encouraged to take part in some form of training in the conduct of human participants’ research. The UW Human Subjects Division offers in-person sessions, access to the online CITI program (see Appendix C), and a CD ROM (Investigator 101) with a variety of short educational modules.¹⁵ The university is putting in place a system where, every three years, all major principal investigators and their staff must be recertified in research ethics education.

As for nursing, there are programs - such as the Indiana University School of Nursing (the only nursing school in the United States that offers the full range of nursing degrees from two-year associate degrees through PhDs and postdoctoral work) – that require all students to take a workshop in research ethics. PhD students also complete a one-hour research ethics course and a research practicum with a funded investigator. They, therefore, have the opportunity to watch how difficult decisions are made, how much

¹⁵ University of Washington Human Subjects Division Training and Education:
<http://www.washington.ed-u/research/hsd/training.html>

researchers comply with grant proposals, and how data are managed (e.g., how outliers are dealt with). This approach is an example of a combination of limited formal education as an adjunct to training through mentorship.

4.0 Research Ethics Education for BSS Investigators

As discussed at the 2005 FOCUS Conference where the topic was *Ethical Issues in Behavioural and Social Sciences Research*,¹⁶ the BSS research community often feels distanced from a system of ethics oversight that may appear to lack understanding of their goals and methodologies. The bureaucracy of research ethics can be seen as an invading and colonizing force in which biomedical models are imposed on the social sciences, making the ethics review system irrelevant (Hamilton, 2005).

There are a number of problems with the current system of ethics oversight from the perspective of the BSS research community:

- Since research conducted by BSS investigators seldom poses any physical danger to participants, the imposition of a system of oversight based on biomedical research risks may not be justified.
- The current system of ethics oversight lacks cultural sensitivity. It does not understand or appreciate BSS methods or research. The goal of BSS research can be *understanding* a social phenomenon from the point of view of the participants, rather than generalizable knowledge. Or, BSS investigators may be engaged in critical research that actually wants to change the world, rather than simply make observations.
- There are indigenous ethics guides to direct the conduct of research (e.g., the Canadian Code of Ethics for Psychologists - see text box), many of which pre-date the TCPS. However, in order to obtain financial support from any of the funding agencies, the TCPS must be followed.

Canadian Code of Ethics for Psychologists (2000)

The Canadian Code of Ethics for Psychologists (2000) is an example of the sort of indigenous guidance document that can provide useful, discipline-specific direction for researchers. The code sets out the ethical principles, values, and standards that guide members of the Canadian Psychological Association, regardless of whether they are acting as scientists or practitioners. It stresses the responsibilities of the psychologist to individuals and society as a whole.

The BSS research community has responded in several ways:

- There is passive resistance among many social scientists. They may sometimes fill out ethics applications according to what they feel is *wanted*, rather than what truly fits their research.
- Some BSS investigators may avoid the research methods that are reputed to be problematic for particular IRBs/REBs, or simply avoid sensitive topics altogether.
- Some research may go underground; that is, it may be conducted without ethics approval.

¹⁶ FOCUS Report on an International Conference on Ethical Issues in Behavioural and Social Sciences Research: http://www.ncehr-cnerh.org/pdf/publications/focus/focus_2005_report_e.pdf

4.1 Responsible Conduct of Research Initiatives from the Council of Graduate Schools

The Council of Graduate Schools (CGS) has undertaken an initiative to discover and implement educational strategies that lead to responsible conduct of research.¹⁷ This began with a research and demonstration project funded by the ORI in which small grants were given to ten institutions to develop and evaluate pilot programs in responsible conduct of research for graduate students in the behavioural and biomedical sciences. There are plans to extend the initiative by funding eight more institutions to develop and implement training programs in the other sciences, with a focus particularly on interdisciplinary programs.

Several best practices have been suggested by the CGS initiative:

1. Establish a high profile permanent advisory board with the most respected researchers on campus in order to (a) assist in the planning of RCR educational strategies, (b) advance RCR proposals to the curriculum process, and (c) promote campus-wide awareness of RCR.
2. Provide many public forums on RCR that feature experts in order to raise the profile of RCR on campus. This will contribute to the ethical “climate” of an institution and may impact behaviour more than professional values or individual ethical commitments taught in RCR courses.
3. Offer two-tiered instruction that has a general interdisciplinary component with students from different disciplines attending, and specific courses or course elements and issues within disciplines.
4. Teach ethical reasoning skills so that students emerging from doctoral programs are capable of, for example, engaging in ethical and public policy debates with regard to issues in their disciplines, and recognizing all dimensions of human integrity that need to be protected in human participant research beyond regulatory requirements.
5. Make RCR training mandatory for graduate students. This will take time and will need to be preceded by gradually embedding RCR requirements into the graduate curriculum, or establishing certificate programs that can initially be offered on a voluntary basis.
6. Develop multilevel assessments of RCR training. For example, identifying the gap between students’ perceptions of what RCR education they are getting versus the faculty perception of what they are giving, may contribute to overcoming resistance to the establishment of more RCR education on campus.

4.2 Lessons from Anthropology

Anthropologists spend a lot of time in the community, developing close relationships with research participants. Such investigations into human behaviour and human phenomena do not necessarily follow a predetermined blueprint for the type of data to be collected; in fact, ethnographer data can be found anywhere and can include personal experiences, observations and conversations that are part of everyday life (Tolich & Fitzgerald, 2006). There is also a sense of needing to give back, particularly in *applied* anthropology, so research is conducted with the goal of contributing to some type of understanding of, or improvement in, problems in the community.

With this type of approach it is important to consider the implications of having contact with participants, as well as the implications of the research in general. The various arms of anthropology have, therefore, developed principles that mirror some well known research ethics precepts such as beneficence and justice (e.g., the Society for Applied Anthropology was the first organization within anthropology to develop a

¹⁷ CGS Responsible Conduct of Research Initiatives: <http://www.cgsnet.org/Default.aspx?tabid=123>

statement of ethics [Meade *et al.*, 1949] and, as of 1983, it has included a strong consent principle in its *Statement on Professional and Ethical Responsibilities*).

Anthropological research necessitates special training of scientists regarding recruitment (e.g., when does a simple conversation end and enrolment of participants begin?), data collection (e.g., how far can an interviewer probe when the topic is sensitive?) and a myriad of other ethical issues (e.g., what are the limits to confidentiality?). It, therefore, follows that anyone involved in the review of this type of research will also require special training to understand the way in which the methodology should be evaluated against usual ethics principles. When assessing the procedure for informed consent, for example, it might be necessary to evaluate whether or not the appropriate “spheres of consent” (such as community leaders; Weijer & Emanuel, 2000) are included. IRBs/REBs will also necessarily want to know how much education in research ethics that BSS investigators (and their teams) have had.

Education could, therefore, include various facets for both IRB/REB members and investigators (prior to finalizing their design):

- Pre-submission consultation with the IRB/REB so that the investigator could be made aware of contentious issues and their potential solutions.
- Communication of standards for methods (many involved in qualitative research are currently involved in standardizing their methods).
- Setting criteria for acquiring an exemption status, or even expedited review.
- Developing ways to ensure that information will be anonymized where appropriate (e.g., with snowball sampling).
- Learning appropriate ways to satisfy the principle of informed consent (e.g., timing and type).
- Recognizing the need for a review that is flexible enough to mirror the plasticity of the iterative design.
- Appreciating that research integrity is not something that can be regulated; therefore, efforts should be made to create a culture that values ethical scientific practices.

5.0 Research Ethics Education for IRBs/REBs

There is evidence to suggest that all researchers – whether biomedical or BSS – want the same things from their IRBs/REBs. They would like to be treated fairly and with respect, and to receive decisions that are rational, just, consistent and timely (Keith-Spiegel *et al.*, 2006). This suggests at least three important streams of education for IRB/REB members:

1. Interpersonal communication: particularly to facilitate productive relationships with investigators. While the *TCPS* (CIHR *et al.*, 1998) and the *Belmont Report* ((National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) espouse principles such as respect and justice in the treatment of research participants, such principles can also be applied to the interactions between IRBs/REBs and investigators.
2. Knowledge of ethical and methodological research issues: including relevant regulations, guidelines and methods associated with the types of research that will come before the board. It may be important to equip IRBs/REBs with information about methods in both biomedical and BSS research, and knowledge of how ethical principles are implemented within each approach.
3. Training in critical thinking: particularly when dealing with situations that are not covered by guidance/regulations, or where there is disagreement or the need to evaluate differing moral standpoints (Loff & Black, 2004).

In Canada, the TCPS (1998) suggests that face-to-face meetings are essential for two reasons: (1) the adequate discussion of research proposals and, (2) the collective education of the REB (Article 1.7). REBs are encouraged to allow researchers to participate in discussions about their proposals and, in so doing, are providing them with a source of education. In addition, REBs are expected to hold educational workshops for members. In fact, according to the TCPS, education and review are seen as the two main roles of REBs.

In the U.S. it has been suggested that the compliance issue (generally overseen by research units in universities) should be separated from education. If educational initiatives are implemented from a graduate school or from a unit that is not in charge of compliance then members of the IRB are not involved in suggesting, implementing or advancing education but are, rather, students in that program. Keeping IRBs separate from education is thus seen as avoiding a type of conflict of interest.

Private or independent IRBs/REBs may not have to face the same issues confronting IRBs/REBs in universities or teaching hospitals. However, it is not necessarily clear how they would acquire ongoing education in research ethics issues.

6.0 The Role of the Community in Research Ethics Education

Communities are not only the source of participants for many investigators; they can also be an educational resource concerning the conduct of research within their environs. A case in point concerns North American Aboriginal communities. There is also a need for the community to learn about the ethical conduct of research when approached by investigators, as in prevention science research.

6.1 Lessons Learned from Aboriginal Communities

Many Aboriginal peoples have felt exploited by investigators who have parachuted into their communities to conduct research and left without appropriate consultation or debriefing. In order to learn to conduct ethical research in aboriginal communities it is necessary, therefore, to establish policies that will both guide investigators and be the basis for education in this area.¹⁸

In Canada, a draft document from the Canadian Institutes of Health Research (CIHR) - *Guidelines for Health Research Involving Aboriginal Peoples* (2006) – has been developed in order to promote mutually beneficial research that will respect the culture and values that Aboriginal people hold dear. The guidelines have undergone an extensive review process with stakeholder constituencies. This review process has produced a number of observations concerning the ethical conduct of research in Aboriginal communities:

- Concerns on the part of Aboriginal communities often stem from a lack of involvement in the research process, a feeling of being mere “objects” of research, a perception of irrelevance to the community, and misrepresentation that could lead into stigmatization. They would, therefore, like to be involved at all stages of the research process from inception to publication.
- Research is value-laden; community involvement can assist the choice of culturally appropriate data collection instruments as well as the interpretation of the cultural or social context.

¹⁸ One useful source of online information is provided by the Aberdeen Area Tribal Chairmen’s Health Board - Research Ethics and Institutional Review Board Resources for Tribes and Researchers - which includes a sample checklist that was developed for tribes to review research protocols according to tribal community values. See: <http://www.aatchb.org/epi/docs/ResearchEthics.htm>

- The desire to have community input at the interpretation/publication stage does not have to infringe on the academic freedom of investigators. It could simply mean allowing for the inclusion of a dissenting view.
- Engendering the trust of Aboriginal communities means supporting a true partnership with investigators. In Canada, this partnership is facilitated by the establishment of the Aboriginal Capacity and Developmental Research Environments (ACADRE) program which is developing a network of supportive research environments across the country.
- Elders are very special to Aboriginal communities as they have enormous wisdom and they are able to give culturally appropriate advice. Their input in the research process can be invaluable.
- Talking circles” are used in Aboriginal communities to discuss issues/problems and their resolutions. This sort of “focus group” could be used prior to the start of any research and would afford the community an opportunity to have input.
- Communities want to see some benefits accrued to them as opposed to just the research enterprise.
- It may be necessary for investigators to obtain group consent (i.e., from the community) as well as individual consent.
- Communities would often like the opportunity to be part of the investigation; therefore, a participatory research approach can be optimal.
- Indigenous concerns over intellectual property need to be explicitly acknowledged and addressed in a research agreement.
- Investigators need to understand and respect the world-view of the Aboriginal community being studied (known as “cultural competence”).
- In order to be fully informed, many Aboriginal individuals need to have all information about the research provided in their own language.
- The secondary use of research data has often been a problem for Aboriginal communities (one of the most infamous cases in Canada was the unsanctioned use of blood samples from the Nuu-chah-nulth). It is, therefore, important to recognize that communities have a proprietary interest in the collection, storage and potential use of data. Re-consent should be obtained if either party would like to conduct further research with the data.
- Aboriginal research samples should be considered *on loan* to the investigator who would retain the samples as *steward* of the data. This is analogous to a licensor agreement between the researcher and the participant or communities, and it recognizes the traditional relationship that Aboriginal individuals have to their body and body parts.
- The research must respect and address the confidentiality and privacy concerns of the community. If there are limits to the degree of confidentiality that can be guaranteed, they need to be specified.
- Investigators should support education and training for Aboriginal peoples in research and research ethics issues so that they can be involved on the research team (e.g., as interviewers) and also be better equipped to understand and evaluate research. In other words, this will help communities develop their capacity to engage in research.

CIHR plays an active role in seeing that investigators conducting research in Aboriginal communities receive the necessary education. For example, CIHR sponsors workshops in academic environments with researchers and IRBs/REBs, participates in conferences (such as FOCUS), and provides resource materials that are useful to researchers and academics teaching courses on research ethics.

6.2 Prevention Science Research

Prevention science research, particularly clinical research, can be conceptualized as a framework that integrates five elements: advocacy and policy, community participation, prevention research, acceptability research, and operations and program development (MacQueen & Cates, 2005). These elements can be coordinated and integrated through all stages of the research, particularly when the community is engaged as both learners of, and contributors to, the process.

There are at least three examples of partnership with communities¹⁹ that investigators can explore:

1. Community consultation: This places an emphasis on representing community voices; investigators must learn to listen in a way that is accepting of new and different perspectives. It is actually more about respect than true partnership but it allows the community – or at least designated leaders – to have input into the research.
2. Community advisory boards: Once again, if the board serves in a truly advisory capacity then it is not a true partnership; however, the notion of a board suggests a longer-term role in the research.
3. Participatory research: This approach gives community members the opportunity to be part of the entire research process from inception to application. It is a true partnership in the sense that the boundaries between investigator and participant become blurry. This approach to community involvement in research can be challenging, particularly when it is a medical study that can have serious consequences in terms of lives that are directly or indirectly affected. Community involvement at this level could also require education in research methods and ethics that is specially designed for the lay person.

7.0 Is Research Ethics Education Effective?

There are few data to suggest whether or not education in research ethics is effective in reducing misconduct. Any attempt to gauge the ratio of violations to the number of people trained is necessarily imperfect because there is no way to know what percentage of actual cases of misconduct is reported due to the inconsistency of the whistleblower system. Unfortunately, multi-institutional surveys designed to investigate self-reported misconduct have usually not tried to assess the ethics education of respondents (Martinson *et al.*, 2005). Depending on the kind of assessment tool chosen, it is more likely that information concerning educational goals will be acquired rather than data to identify the strengths and weaknesses of RCR programs.

Plemmons *et al.* surveyed students who had completed one of eleven different research ethics courses at ten different institutions and they report that “over 75% of the respondents specifically noted that courses were useful in preparing them to recognize, avoid, and respond to research misconduct” but did not have much effect on skills or attitudes (2006).

The work done by Martinson *et al.* (2006) provides convincing reasons to persuade sceptics of the potential effectiveness of RCR training for graduate students. Not only does the study sound an alarm by estimating that 33% of the practising scientists admit to sanctionable behavioural, it identifies some of the motives of scientists for engaging in such behaviour. These motives can be directly addressed in RCR training.

¹⁹ See the *FOCUS Report on an International Conference on Ethical Issues in Behavioural and Social Sciences Research* for more information about community-based research:
http://www.ncehr-cnerh.org/pdf/publications/focus/focus_2005_report_e.pdf

Incidents of serious research misconduct are rare; therefore, it will be hard to prove that education is having a beneficial effect. To complicate impact assessments even further, there are many aspects to courses or even general programs in institutions that might promote RCR. To attribute change to any one kind of activity is problematic.

It has been suggested that it may not be essential to prove the efficacy of RCR education ahead of setting up certain programs as it does not have to be that expensive. An affordable solution might require that a *decent minimum* of 0.1% of every research budget should be directed towards education and training in research ethics and promoting RCR.

8.0 Recommendations

The recommendations that emerged from the discussions concerning learning to conduct ethical research in humans fall into five main categories:

A. Setting the Agenda for Education in Research Ethics

1. The educational agenda associated with learning to conduct ethical research in humans needs to start with an understanding of research ethics, which is part of a greater commitment to the Responsible Conduct of Research (RCR).
2. Education in research ethics is one way of addressing the problem of bad science and should, therefore, be considered an essential part of every graduate and medical curriculum.
3. Education cannot be seen as “add on.” It has to be nurtured from the “ground up” and treated as an integral part of every discipline that engages in research. Only in this way can the ethical conduct of research become part of the larger culture of conducting, understanding and interpreting research.
4. The ultimate goal of ethical review needs to be specified. If the objective is to cultivate a community of teachers and learners who care about research ethics issues, rather than a quick way to rubber-stamp the approval of protocols, then education should be made a priority.
5. There should be an institute requirement that [at least] 0.1% of every research budget should be directed towards education and training in research ethics and promoting RCR. It is an affordable and easy way to support the goal of learning to conduct ethical research in humans.

B. Targets of Research Ethics Education

6. Education in research ethics should target graduate and medical students, researchers at all levels and every member of the research team, those who might be mentors or role models to new investigators, and possibly those who administer grants.
7. Members of IRBs/REBs, as well as administrators and those who write research ethics guidelines, are also in need of research ethics education. Such education should include information about research methods, particularly where behavioural and social sciences are concerned.
8. Researchers can help develop the capacity of communities (e.g., Aboriginal) to engage in research by supporting education and training for community members in research and research ethics issues.
9. All medical students should be taught to understand the ethics involved in good clinical practices associated with human research, even if they do not intend to conduct research themselves. They will still need to understand and interpret research findings in their practice.

C. Approaches to Learning Research Ethics

10. Learning about research ethics has to occur in many different modes and styles, e.g., courses, role-play and mentoring (such as the University of Alberta's Ethics and Scientific Integrity Day - see page 29).
11. Instructors, mentors and other role models in research need to believe in the importance of research ethics for education to be effective.
12. Students will be greatly influenced by the conduct of senior investigators and other research staff in the lab. Leadership from senior investigators – in the form of communicating appropriate norms and establishing responsible research practices – should be encouraged as it will produce quality research and quality researchers. Learning by example is a powerful way to influence students.
13. RCR best practices suggested by the Council of Graduate Schools:
 - I. Establish a permanent RCR advisory board.
 - II. Provide public forums on RCR
 - III. Offer two-tiered instruction: interdisciplinary *and* discipline-specific courses or course elements.
 - IV. Teach ethical reasoning skills.
 - V. Have the ultimate goal of making RCR training mandatory for graduate students.
 - VI. Develop multilevel assessments of RCR training.
14. Students who have been trained to recognize and avoid research misconduct should also be given avenues to pursue their concerns (e.g., an ombudsman).
15. Students should be given the opportunity to discuss problems and case studies in research ethics with professors and colleagues as this encourages ethical reasoning. Critical thinking is usually part of graduate and medical school criteria but the way in which it can be applied to research ethics issues may need additional consideration.

D. The Content of Education in Research Ethics

16. It is important to decide what students need to know, and set appropriate and standardized curricula. Some have even suggested the need for a national curriculum in RCR (but this is not universally accepted as there may be significant institutional differences in the approach to research ethics).
17. Education should be designed to provide both knowledge and skills in research ethics.
18. There are important topics not always included in research ethics education - such as authorship, and how to be completely transparent in data collection - that should be incorporated into courses having to do with RCR.
19. Education and training in research ethics should be largely discipline-specific.
20. Research has identified some of the motives scientists have for engaging in misconduct; these motives should be directly addressed in education. Also, actual cases of misconduct can be used as valuable training tools.

E. Engaging the Academic Community

21. Investigators should be encouraged to conduct research on matters of research ethics, thus creating an atmosphere of collaboration between IRBs/REBs as well as building an empirical base for board decisions that can contribute to educational curricula.
22. The community of academics interested in research ethics might look at ways in which governments or regions could put in place more rigorous systems of ethical oversight (including mechanisms for education), particularly for private IRBs/REBs.
23. Data are needed concerning the effectiveness of different approaches to education and training in research ethics.

University of Alberta “Ethics and Scientific Integrity” Day

The Faculty of Medicine and Dentistry at the University of Alberta holds an “Ethics and Scientific Integrity” day three times a year in order to offer students information about the appropriate conduct of research and other ethical issues. Each day consists of lectures, videos, breakout sessions and discussions; the preceptors are professors. Attendance at the seminar is mandatory for students and counts as five hours towards their ethics training (students are expected to participate in at least eight hours of “structured academic activity”). Participants in the ethics day receive a certificate of completion. It should be noted that there are potential drawbacks to this approach as a day-long seminar can be seen as simply an “add on” to the serious curriculum.

See: <http://www.med.ualberta.ca/integritydays/>

9.0 Conclusion

To be able to conduct research on humans is both a privilege for investigators and a boon to the people who will ultimately benefit from the information acquired through such scientific enquiry. The pursuit of new knowledge and understanding may result in improved treatments for illness, insights that lead to better governmental or institutional policy, an enhanced understanding of culture, history or the arts, and – simply put – some degree of progress in the human condition. While we are accustomed to the notion that investigators need education and training in order to be able to acquire the knowledge and use the skills necessary to conduct excellent research, we are less familiar with the idea that learning to conduct research in an *ethical* manner is also a necessary part of that education.

It is clear that learning to conduct ethical research in humans needs to be an intrinsic part of every educational effort that speaks to the conduct of research. While research ethics can be the topic of a specific course (and this is just one vehicle for the transmission of necessary information), it must not be seen as something that can be tacked on to the end of a program in order to help students write successful IRB/REB applications for their proposals. Having an ethical approach to conducting research begins with an attitude that is translated into every aspect of the research process from the design of a study to participant recruitment to the appropriate interpretation of the data. We may think of research ethics primarily in terms of respect and protection for human participants but it is part of larger context in which the responsible conduct of research is the objective. The respect that must be shown to participants is also necessary for the students who desire credit for their work, or the investigators who need to see fairness in the system of academic rewards.

Education in research ethics is, therefore, vitally important for students planning to be researchers. It is also important for scientists who may have been in the field for a long time and are not up-to-date on ethics issues, all members of the research team, clinicians who need to be able to interpret research and pass on the information to their patients, members of IRBs/REBs, administrators, mentors for students, and lay people who might be targeted as research participants or part of a community wishing to develop their research capacity.

Education can come in the form of courses, parts of courses, observation in the laboratory or field, workshops, discussion groups, online tutorials *et cetera*, and should be offered in a discipline-specific format (see Appendix D). It is generally agreed that education can start with rules and regulations but should also cover theory and practical application. Students need to be provided with both the knowledge and the skills to conduct research in an ethical manner.

While there are few studies to suggest whether or not research ethics education can reduce the frequency and seriousness of incidents of scientific misconduct, it is generally expected that education – along with appropriate guidance and regulation – will have a beneficial effect on the way scientists operate in the 21st century. Leadership in this endeavour must come from universities and other educational institutions, professional standard setting and credentialing organisations, research funding agencies and discipline-specific societies.

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Appendix A: FOCUS Conference Program



An International Conference on Learning to Conduct Ethical Research in Humans: Educational Needs and Models

2006 FOCUS Conference Program

June 1-2, 2006

Washington, DC, USA

Thursday, June 1, 2006

17:30 – 18:45 *Registration and Refreshments*

18:45 – 19:15 **Welcome & Introduction**

Henry Dinsdale, Chair, FOCUS

Ian Shugart, Senior Assistant Deputy Minister, Health Canada (Invited)

Bernard Schwetz, Director, Office for Human Research Protections (Invited)

Session Chaired by Marjorie Speers, Association for the Accreditation of Human Research Protection Programs, Inc

19:15 – 19:35 **Investigator Perspective - Medical**

John Cairns, University of British Columbia

19:35 – 20:00 **Emphasis Social Behavioural Research**

Glenn Griener, President of the National Council on Ethics in Human Research; University of Alberta

20:00 – 20:30 **Discussion**

20:45 – 22:00 *Evening Reception Buffet (Cash Bar)*

Friday, June 2, 2006

8:00 – 8:30 *Registration and Continental Breakfast*

Session Chaired by Barbara McGillivray, University of British Columbia

~ Integrating Ethics of Research in Humans at Various Educational Levels ~

8:30 – 8:50 **Graduate Student** – Paul Tate, Council of Graduate Schools

8:50 – 9:10 **Medical School** – Martin McKneally, University of Toronto

9:10 – 9:30 **University** – Michael Kalichman, University of California

9:30 – 10:00 **Discussion**

10:00 – 10:30 *Refreshment Break*

Session Chaired by Michael McDonald, University of British Columbia

~ Investigator Perspective ~

10:30 – 11:00 **Emphasis Biomedical** - David Korn, Association of American Medical Colleges

11:00 – 11:20 **Nursing** – Marion Broome, Indiana University School of Nursing

11:20 – 11:40 **Graduate Student** – Lida Anestidou, Vanderbilt University Medical Center

11:40 – 12:00 **Discussion**

12:00 – 13:00 *Lunch*

Session Chaired by Joan Sieber, California State University, East Bay

~ Models ~

13:00 – 13:20 **Cultural Anthropology** – *Cynthia Woodson, Research Triangle Institute*

13:20 – 13:40 **Psychology** – *Camille Nebeker, San Diego State University*

13:40 – 14:10 **Discussion**

Session Chaired by Glen Drew, Office for Human Research Protections

~ Community Role in Education and Cultural Competence ~

14:10 – 14:30 **Aboriginal Communities** – *Doris Cook, Canadian Institutes of Health Research*

14:30 – 14:50 **Family Health International** – *Kathleen MacQueen, Family Health International*

14:50 – 15:20 **Discussion**

15:20 – 15:40 **Refreshment Break**

Session Chaired by Moira Keane, University of Minnesota

~ Integrity/Accountability/Institutional/Investigator Interaction ~

15:40 – 16:00 *Nick Steneck, University of Michigan*

16:00 – 16:20 *C. Kristina Gunsalus, University of Illinois*

16:20 – 16:50 **Discussion**

16:50 – 17:15 **Summary and Recommendations**

Marjorie Speers, Association for the Accreditation of Human Research Protection Programs, Inc.

Appendix B: Examples of Organizations Offering Education in Research Ethics

CANADA	
ORGANIZATION	DESCRIPTION
<p>CAREB: Canadian Association of Research Ethics Boards</p> <p>http://www.careb-accer.ca/index.html</p>	<p>CAREB is a grassroots national membership organization intended to represent the interests of all Canadian REBs and to reflect REB perspectives and concerns. In part, their mandate is to help identify the educational and professional needs of REB members and administrators, and provide a collective voice in seeking the resources to support these needs. CAREB holds an annual conference that is preceded by “REB Administrator 101,” a one-day course for new REB administrators on the practical aspects of running an REB office and supporting the work of the REB.</p>
<p>GEREQ (Gestion électronique des données Réseau de sites cliniques)</p>	<p>GEREQ (English name: Electronic Data Management Clinical Site Network) offered training modules for clinical research professionals in both French and English, as well as instructor-led workshops including an introductory Good Clinical Practice course and an intermediate-level ethics course.</p>
<p>Ministère de la Santé et des Services sociaux Training Program in Research Ethics</p> <p>http://ethique.msss.gouv.qc.ca/didacticiel/index.php?lang=en</p>	<p>This training program was developed by the Groupe FEE (Formation en éthique/For Ethics Education) with special emphasis on regulations in Québec, and is founded on two pedagogical strategies:</p> <ol style="list-style-type: none"> 1. On-line tutorial: Enhancement of theoretical knowledge and application of principles by means of questions and dynamic simulation exercises inspired by REB daily activities. 2. Training workshops: Deepening of theoretical knowledge by means of practical activities, the application of the knowledge acquired through web based training, and the exchange of knowledge and experiences between participants.
<p>NCEHR: National Council on Ethics in Human Research</p> <p>http://www.ncehr-cnerh.org/</p>	<p>One part of the NCEHR mandate is to foster education, dialogue and understanding in and among institutions, REBs, researchers, professional personnel, organizations that fund research and the public, on the ethical aspects of research involving human subjects and the implementation of appropriate guidelines. To this end, NCEHR organizes workshops, conferences and site visits as part of their educational program.</p>

UNITED STATES

ORGANIZATION	DESCRIPTION
<p>AAHRPP: Association for the Accreditation of Human Research Protection Programs</p> <p>http://www.aahrpp.org/www.aspx</p>	<p>AAHRPP offers accreditation to institutions engaged in research involving human participants using a voluntary, peer-driven, educational model. AAHRPP seeks not only to ensure compliance, but to raise the bar in human research protections by assisting institutions to reach performance standards that surpass the threshold of state and federal requirements.</p>
<p>ORI: Office of Research Integrity</p> <p>http://ori.hhs.gov/</p>	<p>ORI supports several programs designed to promote education and training in RCR that cover the following instructional areas:</p> <ol style="list-style-type: none"> 1. Data Acquisition, Management, Sharing and Ownership 2. Conflict of Interest and Commitment 3. Human Subjects 4. Animal Welfare 5. Research Misconduct 6. Publication Practices and Responsible Authorship 7. Mentor / Trainee Responsibilities 8. Peer Review 9. Collaborative Science
<p>Poynter Center for the Study of Ethics and American Institutions</p> <p>http://poynter.indiana.edu/</p>	<p>The Poynter Center has extensive experience in designing curricular materials for teaching research ethics and in conducting faculty development workshops in teaching ethics. Every year the Center offers a “Teaching Research Ethics Workshop” to provide training for those involved in teaching research ethics or in administering research programs. The workshop emphasizes a variety of pedagogical approaches to teaching research ethics, through sessions on ethical theory, research ethics, trainee and authorship issues, assessment and evaluation, responsible data management, integrity in research, conflict of interest, and international research.</p>
<p>PRIM&R: Public Responsibility in Medicine and Research</p> <p>http://www.primr.org/index.html</p>	<p>For more than thirty years, PRIM&R offers learning opportunities in the fields of biomedical and social/behavioural/educational research. The goal is to provide current information on the ethics and legal issues related to human and animal subjects protections, as well as to offer best practices and strategies for implementing successful research protection programs. PRIM&R offers conferences, educational programs, Web-based seminars (Webinars), and training materials.</p>
<p>RCREC: Responsible Conduct of Research Education Committee (Merged with the Association for Practical and Professional Ethics on May 1, 2006)</p> <p>http://rcrec.org/index.htm</p>	<p>The mission of RCREC is to provide leadership to the research community in identifying, developing, and promoting programs of education in RCR. This is accomplished by collaborations among institutions, organizations, and federal agencies that have roles and interests in RCR.</p>

Appendix C: Examples of Online Education in RCR/Research Ethics

CANADA		
ORGANIZATION & COURSE TITLE	COURSE DESCRIPTION	AUDIENCE
<p>The Interagency Advisory Panel on Research Ethics' (PRE) online Introductory Tutorial for the <i>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans</i> (TCPS)</p> <p>http://www.pre.ethics.gc.ca/english/tutorial/</p>	<p>The tutorial covers the first five sections of the TCPS:</p> <p>Section 1: Ethics Review; Section 2: Free and Informed Consent; Section 3: Privacy and Confidentiality; Section 4: Conflict of Interest; and Section 5: Inclusion in Research.</p> <p>The tutorial has two case studies. The same case studies appear in each section of the tutorial and allow the user to apply information discussed in the section. The case studies include a commentary so that users can check answers. It ends with a Progress Check.</p>	<p>Both biomedical and social science:</p> <ul style="list-style-type: none"> • Researchers • Research Ethics Board (REB) Members & Administrators • Research administrators • Students • Actual or Potential Research Participants • Members of the General Public • Policy Analysts
<p>McMaster University Research Ethics Tutorial</p> <p>http://www.mcmaster.ca/ors/ethics/faculty_tutorial.htm</p>	<p>Frame of reference for this basic tutorial is the TCPS. List of topics:</p> <ul style="list-style-type: none"> • Research Ethics and Codes of Ethics • The Tri-Council Policy Statement • Defining Research • The Ethical Review Process • Informed Consent • Submitting an Application • The Approval Process • The Ethics of Medical Research • Qualitative Res. in Social/Behavioural Science & Humanities • Sample Cases and questions • Codes of Ethics and Online Tutorials 	<p>Intended for all researchers, (i.e. faculty, students, staff) and members of REBs</p>
<p>McMaster University Tutorial for Researchers Conducting Retrospective Review of Health Records</p> <p>http://ethics.mcmaster.ca/chart</p>	<p>Researchers are asked to complete this brief tutorial to ensure that they are aware of the privacy issues which arise in research involving retrospective review, and to ensure that they are aware of how to complete the Application for Retrospective Review form, so that there will be no delay in the approval process.</p> <p>The tutorial consists of:</p> <ul style="list-style-type: none"> • Guidance for researchers • Several privacy scenarios • A quiz with five questions • A certificate of completion 	<p>Successful completion of this tutorial is required before Applications for Retrospective Review are processed or reviewed by the REBs at either Hamilton Health Sciences or St. Joseph's Healthcare Hamilton.</p>

<p>Ministère de la Santé et des Services sociaux Tutorial in Research Ethics</p> <p>http://ethique.msss.gouv.qc.ca/didacticiel/index.php?lang=en&MoodleSession=8f55b8fcfa057c2010ab5fc178c7da0a</p>	<p>Initiated by the Quebec Ministry of Health and Social Services and created with the contribution of REB members and experts, the training program integrates theory with practice in the broad field of research ethics. Designed to promote better learning with respect to applying theoretical knowledge to practical demands, the training program is founded on two pedagogical strategies:</p> <ul style="list-style-type: none"> • On-line tutorial: Enhancement of theoretical knowledge and application of principles by means of questions and dynamic simulation exercises inspired by REB daily activities. • Training workshops: Deepening of theoretical knowledge by means of practical activities, the application of the knowledge acquired through web based training, and the exchange of knowledge and experiences between participants. 	<p>The overall objective is to meet the specific training needs of REB members and support staff in updating knowledge, and acquiring skills, essential for resolving ethical problems encountered in the course of REB activities.</p>
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UNITED STATES

ORGANIZATION & COURSE TITLE	ORGANIZATION & COURSE TITLE	ORGANIZATION & COURSE TITLE
<p>Family Health International Research Ethics Training Curriculum (RETC) Interactive Web Version</p> <p>http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/index.htm</p>	<p>The curriculum may be used as an interactive self-study program or as a tool for participatory group training. The tutorial is divided into 5 sections:</p> <ol style="list-style-type: none"> 1. Contents: <ul style="list-style-type: none"> • Principles of Research Ethics • Foundations of Research Ethics • Responsible Conduct of Research • Supervision of Research • Special Issues in Research 2. Case Studies [8 reproductive health case studies followed by questions.] 3. Evaluations 4. Slide Masters 5. References 	<p>The tutorial was created for an international audience of both biomedical and social science researchers. Available in English, French, Spanish & Portuguese.</p>
<p>Family Health International Research Ethics Training Curriculum for Community Representatives</p> <p>http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/RETCCREn/index.htm</p>	<p>This curriculum is separated into two parts to facilitate 2 training sessions (with a “Presenters” option for those teaching this course to others):</p> <p><i>Part A</i></p> <p>Section I: Community Participation in the Research Process</p> <p>Section II: Researchers and Sponsors</p> <p>Section III: Ethics Committees</p> <p><i>Part B</i></p> <p>Section IV: Principles of Research Ethics</p> <p>Section V: Informed Consent</p> <p>Section VI: Research Ethics Documents</p>	<p>Designed to educate community representatives (either advisors to the research or members of an REB/IRB) about their roles and responsibilities. Available in English, French, Spanish & Portuguese.</p>

<p>National Institutes of Health Protecting Human Subjects - Computer Based Training for Researchers and Research Staff (NIH only)</p> <p>http://ohsr.od.nih.gov/cbt/cbt.html</p>	<p>It provides important information for all investigators, even those working with tissues or specimens derived from human sources, to understand when proposed research triggers regulatory and policy requirements.</p>	<p>Completion of this CBT course is an educational requirement for all researchers in NIH's Intramural Research Program (IRP), and other NIH employees who conduct or support research involving human subjects.</p>
<p>National Institutes of Health Computer Based Training Course for NIH IRB Members</p> <p>http://ohsr.od.nih.gov/IRBCBT/login.html</p>	<p>This course provides information to NIH IRB members about their roles and responsibilities. Completion of this CBT is required by NIH IRB members. It contains three lessons:</p> <ul style="list-style-type: none"> • Lesson 1: Introduction • Lesson 2: Using NIH IRB Review Standards • Lesson 3: Continuing IRB Review, IRB Minutes, and Other Issues 	<p>Designed primarily for NIH IRB members but its content is also useful for clinical researchers submitting protocols for review by an NIH IRB.</p>
<p>National Cancer Institute Tutorial - Human Participant Protections: Education for Research Teams</p> <p>http://cme.cancer.gov/c01/nih_intro_01.htm</p>	<p>Presents information about the rights and welfare of human participants in research. The two-hour tutorial is designed for those involved in conducting research involving human participants. It satisfies the NIH human subjects training requirement for obtaining Federal Funds. The training module is divided into sections:</p> <ul style="list-style-type: none"> • History • The Basics • Informed Consent • IRB Review • Ongoing Protections • International Research • Also includes Glossary, Resources and Faculty 	<p>Intended for use by those involved in the design and conduct of biomedical and behavioural research involving human participants, including:</p> <ul style="list-style-type: none"> • Principal and Associate Investigators • Nurse coordinators • Data managers • Statisticians
<p>Federal wide Assurance Training</p> <p>http://137.187.172.153/CBTs/Assurance/login.asp</p>	<p>Any institution engaged in federally conducted or supported human subjects research must commit itself in writing to the protection of those subjects. This written commitment is called an Assurance of Compliance. For human subjects research conducted or supported by the Department of Health and Human Services (HHS), the Office for Human Research Protections (OHRP) must approve an institution's Assurance before the funds can be awarded and human subjects research can begin. The Federalwide Assurance (FWA) is the most common type of assurance approved by OHRP. This tutorial consists of three modules:</p> <ol style="list-style-type: none"> 1. HHS Regulations & Institutional Responsibilities 	<p>The purpose of the training modules is to ensure that the three key individuals (The Institutional Signatory Official, the IRB Chair, and the Human Protections Administrator) are aware of the responsibilities that must be fulfilled under an FWA. As such, the modules focus on these responsibilities; general topics such as ethics and the regulations are only given a cursory review. These modules were not designed or intended to serve as general training on human subject</p>

	<ol style="list-style-type: none"> 2. Investigator Responsibilities & Informed Consent 3. Human Protections Program Administration & IRB Responsibilities 	protections.
<p>University of Miami and the Fred Hutchinson Cancer Research Center CITI (Collaborative IRB Training Initiative) Course in the Protection of Human Research Subjects</p> <p>https://www.citiprogram.org/default.asp</p>	<p>Program consists of a Basic Course of 12 modules for Biomedical investigators, 11 modules specifically prepared for Investigators conducting Social/Behavioural research and 5 General Interest modules. CITI also offers case-based and abbreviated "Refresher Courses" for re-certification purposes. A multi-language site, targeting international researchers has also been made available.</p>	<p>Meant to assist research investigators, IRB/Ethics Committee members and research staff who may not use English as their first language and who are involved with US federally funded research that involving human research subjects outside the US. Chinese and Spanish translations of the CITI modules on history, ethical principles, US regulations and informed consent issues are available at the site.</p>
<p>Johns Hopkins School of Public Health (JHSPH) Committee on Human Research (CHR) Online Human Subjects Training Module</p> <p>http://www.jhsph.edu/CHR/TrainingModule</p>	<p>Most of the information presented in the training module has been adapted or taken directly from the Federal regulations and the DHHS Protecting Human Research Subjects, Institutional Review Board Guidebook and the Office for Human Research Protections guidance and educational materials. The training module has 12 sections:</p> <ol style="list-style-type: none"> 1. Introduction 2. History 3. Assurances 4. Roles and Responsibilities 5. IRB Review 6. Clinical Research 7. Social/Behavioural Research 8. International Research 9. Summary 10. References 11. Glossary 12. Evaluation 	<p>Generally, all investigators, collaborators, consultants, subcontractors, students, staff and other key personnel who will be involved in human subject's research, must complete the training program prior to submitting an application to CHR for research that will be conducted or supported by JHSPH.</p>
<p>Columbia University Responsible Conduct of Research Online Courses</p> <p>http://ccnmtl.columbia.edu/projects/rcr/</p>	<p>Six online RCR courses are offered:</p> <p>COURSE 1: Conflicts of Interest COURSE 2: Mentoring COURSE 3: Responsible Authorship and Peer Review COURSE 4: Research Misconduct COURSE 5: Collaborative Science COURSE 6: Data Acquisition and Management</p>	<p>Education in RCR is aimed at all participants in the conduct of research at the University, so that they have a basic understanding of all research compliance and integrity issues and more in-depth knowledge in those areas most directly related to their position and/or field of research.</p>
<p>University of Alaska Fairbanks Web-Based Responsible Conduct of</p>	<p>The tutorial is intended to promote the integrity of the university's research community.</p>	<p>Everyone engaged in research activities at UAF, irrespective</p>

<p>Research (RCR) Course</p> <p>http://www.uaf.edu/ori/RCR_Course/about.html</p>	<p>Modules are designed to address the core issues for both responsible conduct of research and for maintaining the integrity of the research record. Email discussion groups are also a significant component of this course. Nine modules are currently offered:</p> <ol style="list-style-type: none">1. Research Misconduct2. Data Management3. Use of Animal Subjects4. Use of Human Subjects5. Conflicts of Interest and Commitment6. Authorship7. Publication and Peer Review8. Collaboration and Mentoring9. UAF Proposal Submission & Grant Management	<p>of discipline, should have a reasonable understanding of the tutorial topics, i.e. faculty, staff, students, administrators, volunteers, or visiting investigators as well as members of Ethics and Safety Committees who review and monitor research and teaching activities.</p>
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Appendix D: Types of Activities Contributing to Learning to Conduct Ethical Research

