

Mechanisms for Compliance with ABS by the Academic Research Community (Canada)

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University scientists are key intermediaries between several different actors. Ethnobotanists, for example, are both investigators and brokers of genetic resources and related traditional knowledge for universities, governments, industry and wider society.¹ Their science takes place at the complex interface of ethics and law, governed by institutional research policies that must incorporate evolving sets of ethical and legal standards at the international, national, and local levels. These institutional research policies are worth examining as a potential mechanism for incorporating new access and benefit-sharing (ABS) policy and facilitating compliance with ABS by the academic research community.² This paper focuses on the Canadian context. Each country will have its own policies and institutional structures, which may be quite different than what is described here, so the following analysis should be viewed as one example, perhaps providing a stimulus for similar analysis of university policies within other countries.

In ethnobotanical research there are obvious links between genetic resources and traditional knowledge.³ Other types of research involving genetic resources may or may not *directly* use traditional knowledge, but there are still often indigenous cultural interests in the research based on traditional uses (either similar or competing), or claims to a given geographical area (e.g., traditional territory) where genetic resources may be collected. Given the inextricable connection between biological diversity and traditional knowledge that is evident in Aboriginal worldviews, it would be prudent (at least within Canada) to assume there are indigenous cultural interests, if not rights, in most research involving genetic resources, whether on ethical, legal or political grounds. Likewise, while some biodiversity research is overtly commercial in nature (e.g., bioprospecting), the goals of academic research are often non-commercial. However, most data flows (directly or indirectly) into the private sector and is available for commercial purposes sooner or later. Therefore, directly or indirectly, intentionally or not, research involving genetic resources and traditional knowledge facilitates knowledge and resource appropriation through research, publication, or sponsorship arrangements, even when the researchers' intentions are purely academic.

University expectations for research (e.g., conceptions of benefits, harms, risks and responsibilities) and application of research policies are influenced by whether or not

¹ There is no single agreed definition of "traditional knowledge". In this paper, it refers to the knowledge, beliefs, innovations, and practices based on customary uses and associated cultural practices and traditions of indigenous peoples, usually transmitted through oral tradition and first-hand observation (CBD 1992, Laird 2002).

² The academic research community refers to university scientists and graduate students who conduct research, and university administrations that develop and oversee research policies.

³ Ethnobotany is the study of inter-relationships between humans and plants, most often involving indigenous peoples and their traditional plant knowledge and resources.

indigenous peoples are *directly* involved, whether the research is national or international in scope, and whether it is primarily academic or commercial in nature. University research policies that are particularly relevant to research involving genetic resources and traditional knowledge, including: (i) ethics policies for research involving humans, and (ii) intellectual property (IP) ownership policies.

Effective national ABS policy must explicitly address the complexity and inter-relatedness of ethical, legal and political considerations in scientific research involving genetic resources and traditional knowledge. But how and at what level should new ABS policy be developed and implemented to facilitate compliance by the academic research community? With this question in mind, this paper examines the existing institutional structures for Canadian University research policies. Two potential areas to target with regards the incorporation of ABS policies into the university system are: (a) national and institutional human research ethics policies; and (b) institutional IP ownership policies. Outside of the university structure, additional target areas include: (c) ethical codes of professional associations and academic societies; and (d) community research protocols. The merits and challenges of these proposals are briefly outlined below.

Human Research Ethics Policies

Existing structures.

Within Canada, all university research that involves humans (e.g., experiments, interviews, surveys) must equal or surpass a national ethics standard called the *Tri-Council Policy Statement for Research Involving Humans*⁴, developed in 1998 and administered through the three federal granting councils.⁵ Compliance with the national ethics standard is mandatory for all universities receiving funding from the granting councils. Implementation is at the institutional level, through university research ethics boards (REBs) that review and approve or reject proposals for research involving humans.⁶ Most institutions and their REBs make a significant effort to educate researchers about ethical considerations in research and assist them in addressing any shortcomings in their proposals. There is considerable incentive for compliance at individual and institutional levels as depending on the source and severity of non-compliance, federal funding support could be withdrawn from a specific project or the entire university.

Prior informed consent (PIC) (in this case referred to as “free and informed consent”) is a key principle of university ethics requirements at the national and institutional levels. In principle, PIC is conceptualised as an *ongoing* process that begins before research is initiated

⁴ Policy available at <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

⁵ The three granting councils are the Social Sciences and Humanities Research Council (SSHRC), the Natural Sciences and Engineering Research Council (NSERC) and the Canadian Institutes for Health Research (CIHR).

⁶ REBs are typically comprised of university faculty and community members serving in a volunteer capacity, with administrative support provided by the university.

and extends throughout the research process.⁷ However, in practice, evidence of PIC typically follows a contractual model, i.e., a consent form signed by individual participants or designated representatives of organizations at the onset of research. Existing policy regarding collective PIC (e.g., some research involving traditional knowledge) is recognized as seriously inadequate and is currently under revision at the national level.⁸ Community-level processes for obtaining consent from indigenous peoples (e.g., customary laws and community protocols) are being given serious consideration in new PIC policy development. The role of community-level REBs (e.g., tribal committees) for reviewing research involving specific Indigenous groups is also being given due attention.

Applications to ABS

In cases where traditional knowledge for biodiversity research is provided by indigenous peoples, ABS policy requirements would overlap with those of existing national human research ethics policies (e.g., PIC requirements, due acknowledgement of source, sharing of benefits). In such cases, the human research ethics aspects of ABS policy could fall under the jurisdiction of the three federal granting councils, either being developed in conjunction with (i.e., as a new section of) the *Tri-Council Policy Statement on Research Involving Humans* or as a separate and parallel *ABS Policy Statement*. Similar to human research ethics, an overarching national ABS policy could serve as the minimum standard for all university research involving genetic resources and traditional knowledge. Compliance would be a mandatory prerequisite to qualify for federal funding. Individual universities could expand their current research ethics policies and review processes to incorporate ABS requirements. Individual research proposals would be approved or rejected by REBs, and researcher awareness would be increased by the educative approach that most universities take in helping researchers to revise non-compliant research proposals.

Benefits would include building on national and institutional structures that are already in place rather than creating new frameworks, as the latter would require significant time and cost. Incorporating ABS issues related to research involving traditional knowledge into human ethics research processes would increase the awareness of the complexity in researcher/institutional/Nation state/Indigenous rights issues in biodiversity research, which could influence wider policy development on PIC and benefit-sharing. Challenges would include the need to educate REBs on new ABS policy and the potential of over-burdening institutional REBs with heavier workloads as these are typically voluntary positions held by full-time faculty and community members. Under current policies, only research that *directly* involved indigenous peoples (e.g., through interviews, surveys) would fall within the realm of human research ethics; research based on published traditional knowledge would not.

⁷ The *Tri-Council Policy Statement* says “consent must be freely given and may be withdrawn at any time” (Section 2, Article 2.2, Paragraph 1), which is interpreted by most institutional REBs as meaning research participants can withdraw their participation from the research at any time. This may also include withdrawing their contributions.

⁸ The *Tri-Council Policy Statement* does include a section on research involving Aboriginal peoples (Section 6) but it was not developed with the participation of Aboriginal representatives and so is in abeyance until appropriate consultation has been undertaken. Currently, a major revision is being facilitated by a new national Aboriginal Ethics Working Group (comprised of Aboriginal Elders and scholars, and some non-Aboriginal scientists), coordinated by CIHR’s Institute for Aboriginal Peoples Health.

Intellectual Property Ownership Policies

Existing structures

In contrast with the national research ethics requirement, which is intended to be implemented consistently across all publicly funded Canadian universities, there is no overarching IP policy for universities. Each university independently determines its own IP ownership policies, in accordance with Canadian and international law. In general terms, IP ownership policies of most universities may be categorised as “institution as owner” or “inventor as owner”. That is, while the researcher is recognized as the creator or inventor, some universities insist on transfer of ownership rights if intellectual property protection (such as a patent) is sought or if an invention is licensed or commercialized.⁹ Other universities simply require a sharing of any revenues as compensation for the infrastructure that they have invested in the research and/or commercialization process. Agreements among inventors and between institutions to specify inventorship, ownership, commercial rights and profit sharing are typically contractual in nature, facilitated in-house by university technology transfer offices.

Applications to ABS

Universities in Canada could directly incorporate intellectual property aspects of national ABS policy into their institutional IP ownership policies. Inventive and commercial rights of indigenous communities, the Nation state and other appropriate entities would be explicitly recognised through contractual agreements with researchers and their sponsoring institutions, using existing (or modified versions of existing) contract templates.

Benefits would include building on institutional structures that are already in place (e.g., administrative assistance, contract templates, in-house legal and business expertise) and increasing the institutional awareness of the complexity in researcher/institutional/Nation state/indigenous rights issues in research involving genetic resources and traditional knowledge. A significant challenge would include dealing with the diversity in IP ownership policies across Canadian institutions. For example, institutions that require a transfer of ownership rights from inventor to institution as a pre-requisite to intellectual property protection, licensing, and commercialization may not provide a flexible enough negotiating environment to accommodate the interests of all stakeholders, particularly when the traditional knowledge of indigenous peoples is involved. In fact, this situation raises a potential conflict between researchers’ obligations to indigenous participants in research under national human research ethics policy and researchers’ obligations to their sponsoring institutions under their institutional IP ownership policies.¹⁰ The mandate of many university technology transfer offices includes education of researchers through seminars, printed and electronic information materials, and meetings, so educative outreach opportunities to discuss ABS policies and issues more broadly with university scientists also exist.

⁹ Copyright tends to be the exception and is more often vested in the creator, unless the work was commissioned by the university.

¹⁰ For further discussion see Bannister (in press).

Extra-institutional Codes of Ethics and Research Guidelines

Existing structures

In addition to their institutional research ethics requirements, many scientists are obliged through voluntary membership to abide by the ethical research standards of national or international professional associations and academic societies. Professional associations (e.g., medicine, engineering, law, education) have enforceable mechanisms for disciplinary action against members while academic societies (e.g., anthropology, archaeology, sociology, ethnobiology, pharmacognosy, chemistry, biology) take a more educative approach to ethical research practices, largely relying on compliance through peer pressure and individuals' concerns about their own reputations. Some societies use formal Codes of Ethics to articulate their ethical standards¹¹, while others use guidelines, position papers, or resolutions to set out expectations for their members.¹² Most of these ethical standards are considered "living documents", thus are subject to periodic revision as ethical and legal considerations in research evolve.

Applications to ABS

Relevant professional associations and academic societies could be strongly encouraged to incorporate the underlying principles of ABS policy into the ethical requirements for their members. Given the significant uncertainty that unresolved ethical and legal issues have created for research involving genetic resources and traditional knowledge, more explicit guidance on some of these through ABS policy would likely be welcomed by most organizations.

Benefits of targeting associations and societies would include high visibility and educative opportunities for generating awareness of ABS issues, and the ability to reach individuals who fall outside the institutional structures discussed previously.

¹¹ Ethical standards specified in *Codes of Ethics* include those of the American Anthropological Association (<http://www.aaanet.org/committees/ethics/ethics.htm>), International Society for Ethnobiology (<http://guallart.anthro.uga.edu/ISE/soceth.html>), Society for Economic Botany (<http://www.econbot.org/ethics/>), Society for Conservation Biology (www.conbio.org/2004/MembersMeeting/Ethics_Statement_2004_07.pdf), Society for Environmental Toxicology and Chemistry (http://www.setac.org/htdocs/who_code.html), American Institute of Chemists (<http://www.theaic.org/DesktopDefault.aspx?tabid=46>), and American Chemical Society (<http://www.chemistry.org/portal/a/c/s/1/acdisplay.html?DOC=membership\conduct.html>).

¹² For example, the American Society for Pharmacognosy has adopted membership *Guidelines for Interactions with Source Countries* (see *Journal of Natural Products* 1997, 60, 654-655), which consider issues related to consent, compensation, conservation, and the rights of Indigenous communities. A technical report on medicinal chemistry prepared by the International Union of Pure and Applied Chemistry (<http://www.iupac.org/reports/1996/6812andrews/index.html>) considers issues such as access, benefit-sharing and intellectual property rights in relation to use of biodiversity for natural products development. Position statements of the American Folklore Society on ethics and human subjects (<http://www.afsnet.org/aboutAFS/ethics.cfm>) outline specific responsibilities to protect the welfare of participants in ethnographic research. The International Chemical Society has adopted conservation and reciprocity-based principles embodied in its *Göteborg Resolution* (<http://www.chemecol.org/society/about.htm>).

Community Protocols

A relatively new phenomenon in Canada and some other countries (e.g., Australia) is the emergence of local research protocols developed by indigenous groups or research organizations that work closely with such groups. These protocols tend to specify local expectations and conditions for research, based on a combination of customary laws and traditional practices, as well as practical realities of contemporary life. Community protocols are increasingly being used to define relationships between indigenous communities and outside researchers.¹³ Assuming ABS policy was developed with appropriate participation of indigenous groups and collaborating research organisations (and therefore had their support in principle), these groups could be encouraged to incorporate ABS policy into their research protocols. This would thereby strengthen local-national policy links by generating further awareness and consistency in policies among users and providers of genetic resources.

ABS as a Catalyst for Integrated Policy Evolution

There is an obvious need for an over-arching national ABS policy that is tailored to Canadian needs and yet is consistent with an international ABS regime. The substance of such a policy has yet to be determined through appropriate national dialogue within Canada, but it will have to address ethical, legal and political dimensions of research involving genetic resources, especially when research also involves traditional knowledge.

This paper addresses one possible framework for the implementation of a national ABS policy, i.e., entrenching ABS policy into well-established university review processes that have built-in compliance mechanisms. This is proposed as a partial strategy to facilitate compliance by the academic research community, including university scientists, students and administrations. Beyond these institutional structures, ABS policy could, foreseeably, also be incorporated into the ethical standards of relevant professional and academic organizations, as well as local research protocols developed at the community level. Assuming the substance of a national ABS policy is developed collaboratively and with these diverse interests in mind (a formidable task), the academic research community and indigenous groups alike would likely welcome the increased certainty in expectations about ABS that such a standard would offer.

There is an additional and significant advantage in bringing ABS policy into the proximity of university research policy. It would serve as a useful context for addressing potential conflicts between research ethics and IP ownership policies in commercially oriented research that involves both genetic resources and traditional knowledge. This could provide the necessary

¹³ Some examples are the *Code of Ethics for Researchers Conducting Research Concerning the Ktunaxa Nation* (Canada), the *Namgis First Nation Guidelines for Visiting Researchers/Access to Information* (Canada), *Principles and Guidelines for Researchers Conducting Research With and/or Among Mi'kmaq People* developed by the Mi'kmaq Ethics Watch (Canada), *Guidelines for Respecting Cultural Knowledge* published by the Alaska Native Knowledge Network and adopted by the Assembly of Alaska Native Educators (Alaska), *Traditional Knowledge Research Guidelines* prepared by the Council of Yukon First Nations (Canada), and *Guidelines for Ethical Research in Indigenous Studies* developed by the Australian Institute of Aboriginal and Torres Strait Islander Studies (Australia),

catalyst for a more integrated approach to co-evolution of university research ethics and IP ownership policies in Canada, encouraging research partnerships by leading to more uniformly ethical and equitable treatment of all interests in the research.

References

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