

Beyond Consent: Respect for Community in Genetic Research

Derek J Jones, *McGill University Faculty of Law, Montreal, Quebec, Canada*

Paula L Bush, *Department of Family Medicine, McGill University, Montreal, Quebec, Canada*

Ann C Macaulay, *Department of Family Medicine, McGill University, Montreal, Quebec, Canada*

Based in part on the previous version of this eLS article 'Community Consent for Genetic Research' (2005) by Charles Weijer.

Paralleling the broadening of scientific thought occasioned by the human genome project, calls have been sounded to expand research ethics to include a principle of 'respect for community' in genetic research. The principle is responsive to a history of genetic research that has harmed some groups. The principle recognises that communities hold dignitary interests, values and rights. For such reasons, it has gained recognition in national and international health research ethics norms. To help translate respect for community into research practice, we identify selected ethics elements and research approaches, including: collaborative community research; jointly defining research priorities and questions; informed consent; joint interpretation and dissemination of results; community ethics deliberations and fair benefit sharing. Implementing such elements presents challenges that merit interdisciplinary study, pluralistic debate and analysis. With such work, we project a future with fuller recognition of respect for community as an ethical principle and duty in human research ethics.

Introduction

Over the last quarter century, the conception and implementation of the Human Genome Project have given rise to issues that have helped to evolve ethical thought on genetic research involving human participants (Greely, 2001). This parallels trends in the broader context of health research, where research ethics have evolved from an almost

eLS subject area: Bioethics & Philosophy

How to cite:

Jones, Derek J; Bush, Paula L; and Macaulay, Ann C (May 2014) Beyond Consent: Respect for Community in Genetic Research. In: eLS. John Wiley & Sons, Ltd: Chichester.
DOI: 10.1002/9780470015902.a0005179.pub2

Advanced article

Article Contents

- Introduction
- Respect for Community: An Evolving Principle
- Why Respect?
- Recent and Emerging Developments
- Ethical Concepts to Translate 'Respect for Community'
- Standing Questions and New Challenges
- Acknowledgment

Online posting date: 15th May 2014

exclusive focus on individuals to ethical issues and principles that touch families, groups and communities.

For instance, nearly a decade ago in this encyclopedia, an ethicist who has devoted considerable attention to research involving Indigenous peoples called for a principle of respect for communities (Weijer, 2003). He did so finding that an ethics framework of respect for persons, beneficence and justice largely ignores community values, welfare and choices.

How has the principle of respect for communities resonated and been applied? In the decade 2003–2013, more than a dozen international organisations and national ethics entities outlined guidelines or statements on genetic, biomedical and population research. International non-governmental medical entities, specialised United Nations and international governmental agencies, and nations including India, Canada, New Zealand, Nigeria and Australia have produced new or revised relevant guidelines. After summarising this historic evolution and portraying sample developments, we identify ethical process and structures that help to translate respect for communities into genetics research.

Respect for Community: An Evolving Principle

Research regarding groups has long presented special ethical issues and responsibilities. As early as the 1970s, research ethics guidelines addressed the challenge. For instance, 1977 Ethics Guidelines for Research with Human Subjects from the Social Sciences and Humanities Research Council of Canada noted that research involving cultural and ethnic groups involve 'special application of ethical principles' that may require 'a different ethic'. The guidelines recognised the welfare, integrity and rights of what it termed 'the collective'.

Table 1 suggests that themes sounded in such early guidelines would resonate beyond Canadian social sciences research towards evolution in the international community

Table 1 Respect for Communities – Sample Interdisciplinary Ethics Policy Milestones

Association of Canadian Universities for Northern Studies 1982^a

“[R]esearch must respect the privacy, dignity, language, traditions and standards of the people”

Society for Applied Anthropology (US) 1983^b

...to the communities ultimately affected by our actions we owe respect for their dignity, integrity and worth

Council for International Organization of Medical Societies, 1991^c

The community to be studied should be represented in the ethical review process. This is consistent with respect for the culture, the dignity and self-reliance of the community...

Royal Commission on Aboriginal Peoples, Canada 1993^d

These guidelines have been developed to help ensure that, in all research sponsored by the Royal Commission on Aboriginal Peoples, appropriate respect is given to the cultures, languages, knowledge and values of Aboriginal peoples, and to the standards used by Aboriginal peoples to legitimate knowledge

UNESCO, Universal Declaration on the Human Genome and Human Rights 1997^e

No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people

World Health Organization, 2003^f

Health research involving Indigenous Peoples, whether initiated by the community itself or by a research institute, needs to be organised, designed and carried out in a manner that takes account of cultural differences, is based on mutual respect, and is beneficial and acceptable to both parties

India 2006^g

Since genetic research gives rise to information applicable to the community from which the participants were drawn, ‘group consent’ will have to be taken from culturally appropriate authority like community head...

United Nations Declaration on the Rights of Indigenous Peoples, 2007^h

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources

Australia 2007ⁱ

Respect for human beings is recognition of their intrinsic value... Respect also requires having due regard for the welfare, beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in research

World Health Organization, 2011^j

Duties to respect and protect communities require examining by the REC and ... are aimed at minimising ... negative effects on communities such as stigma or draining of local capacity, and promoting, positive effects ...

^aACUNS, Ethical Principles for the Conducts of Research in the North, 1982.

^bStatement of Ethical and Professional Responsibilities, 1983.

^cCIOMS, International Guidelines for Ethical Review of Epidemiological Studies, 1991, p.72.

^dRCAP, Ethical Guidelines for Research, 1993.

^eUNESCO, Universal Declaration on the Human Genome and Human Rights, 1997, article 10.

^fWHO, Indigenous Peoples & Participatory Research, 2003.

^gIndian Council of Medical Research, Ethical Guidelines for Biomedical Research on Human Participants, 2006, p.66.

^hUN. Declaration on the Rights of Indigenous Peoples, 2007, article 31.

ⁱAustralia National Statement on Ethical Conduct in Human Research, 2007, section 1.10.

^jWHO, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

over the next decades. Indeed, the excerpts indicate that a principle of respect for groups/peoples/populations/communities has historically flowed from three sources beyond genetics: ethical guidance on anthropological and social sciences research, research involving Indigenous peoples and epidemiological and population-based research. Like genetics, these research domains may implicate cross-cultural, interdisciplinary and international dimensions. The early recognition and evolution of the principle in

these domains have helped it to germinate into genetics research.

Why Respect?

Experience and insight from evolving ethical thought help to identify leading rationales for the principle of respect for community. Research in genetics and the kindred fields

noted above encounter a pragmatic insight: research implicating families, groups and communities presents ethical issues, in addition to protection of the individual (Gostin, 1991; Weijer, 2003). Beyond the constraints of individualism (Widdows, 2009), the principle of respect advances important moral precepts. Respect for community: (1) embraces ethical pluralism, by recognising cultural and ethnodiverse values that help to rethink and recast established ethics frameworks (**Table 1** and **Table 3**); (2) recognises that communities may hold dignitary interests (**Table 1**) and that the dignity and welfare of communities may be harmed (National Bioethics Advisory Commission, 1999); (3) recognises the moral and legal rights of communities and corresponding duties of research professionals and institutions (**Table 1**); (4) responds to historic incidents of genetic biopiracy, stigmatisation and disrespect historically visited upon some communities and groups (Arbour and Cook, 2006; Santos, 2008) and (5) propounds a modern view of research justice for future relationships with communities.

Recent and Emerging Developments

Developments in the decade 2003–2013 influence the continuing evolution of respect for community in human genetic research. They range from biobanking and genomic epidemiological research to trends in community ethics processes and consent. Some of these are elaborated below. Here we sketch trends in research ethics policy and associated legal developments, as indicative of international recognition of the principle and supporting roles for the law.

Ethics policy trends

Table 3 captures new or revised national and international ethics policy statements on health or biomedical research articulated between 2003 and 2013. Some of these explicitly refer to respect for community or its substantial equivalent (e.g. respect for community culture, knowledge, customs, codes, and governance). For instance, the 2011 health research ethics guidelines from the World Health Organization refer to “duties to respect and protect communities...”. Others, such as the Declaration of Helsinki, do not speak of respecting communities, but of protecting ‘vulnerable groups’ (**Table 3**). Finally, although making no explicit reference to the principle of respect for communities, some discuss elements expressive of the principle. For example, the United Nations Educational, Scientific and Cultural Organization (UNESCO) and Uganda do not use the term, but their policies address benefit sharing, community consultation, community research ethics processes, or similar elements expressive of respect. Taken together, the explicit or implicit adoption of respect for community indicates growing emergence of the principle in national and international ethical

standards for research. **See also:** [Codes of Ethics for Genetics Professionals](#)

Legal developments

Three recent international examples illustrate the roles the law may play in advancing the ethical principle of respect for communities in genetic research. First, the 2010 revision of the New Zealand ethical guidelines for research with Indigenous peoples draws on legal principles from a founding treaty between the government and its Indigenous citizens (Health Research Council of New Zealand, 2010). The guidelines recognise genetic research with Indigenous peoples can prove contentious and urge incorporation of Treaty principles of partnership, participation and protection into the research ethics process. These principles echo key elements of collaborative research (**Table 2**).

Second, the genetic isolation and homogeneity of the population of the Canadian province of Newfoundland and Labrador has made this community the subject of intense genetic research (Rahman *et al.*, 2003). In 2011, legislation and implementing regulations took effect, establishing a provincial Health Research Ethics Authority to centralise research ethics committee reviews, standards, processes, and resources (Newfoundland and Labrador, Health Research Ethics Authority Regulations, Regulation 57/11, 2011; Newfoundland and Labrador Health Research Ethics Authority, 2012). This responds to concerns of genetic misadventure and critiques of insufficient oversight and regulation of genetics research for the province’s unique genetic patrimony (Pullman, 2005).

A third classic role of the law is illustrated in the US case of *Havasupai versus Arizona State University (ASU)*. The Havasupai Indian tribe, concerned with its high prevalence of type 2 diabetes, donated blood samples to an ASU geneticist to study the genetic basis of diabetes. More than a decade later, in 2004, the tribe brought suit claiming that – without its knowledge or explicit consent and in violation of its cultural beliefs – the geneticist shared deoxyribonucleic acid (DNA) samples with other researchers to conduct potentially stigmatising research on inbreeding, schizophrenia and evolutionary genetics (Mello and Wolf, 2010). The geneticist and the University claimed the nondiabetes research accorded with signed consent forms to study ‘the causes of behavioural/medical disorders’ (Harmon, 2010). Significant violations of informed consent are unethical, cause dignitary harms and violate human rights (The Nuremberg Code 1996; UNESCO, 2005). In this instance, the ethico-legal dispute over consent alleged violation of physical, spiritual and cultural integrity. In 2010, under a court-approved settlement, the University apologised, paid monetary compensation and returned remaining blood samples to the tribe. This parallels a previous dispute over use, control or ownership of Canadian Indigenous blood samples in genetic research (Arbour and Cook, 2006; Jones, 2001). Because the US case implicated the courts, it illustrates the reactive role of the law as an arbiter of significant

Table 2 Collaborative community research: rationales and principles from participatory research and community engagement*Rationales*

1. Respects rights, welfare, values, culture and peoples
2. Builds effective relationships
3. Recognises and nurtures complementary researcher–community knowledge – views, interests, ideas, experience and expertise
4. Enhances relevance, quality and uptake of research
5. Mobilises community understanding, involvement and assets
6. Jointly identifies and manages risks; maximises opportunities and benefits
7. Promotes self-determination, empowerment and protection of communities

Principles

Mutual respect

Encourages respect & collaboration between researchers & communities

Duty to engage

Researcher engages community across the continuum of research collaboration: from dialogue & consultation, to authorization, to negotiated research partnership agreements

Equitable research partnership

Shared decision-making and co-governance of the research process

- Sharing & allocating roles, funds, responsibilities & powers
- Developing written guiding principles/codes of research ethics^a
- Shared design & conduct of research
 - Setting research agenda(s), purpose, goals & questions
 - Institutional and community ethics review of proposed research
 - Collecting, analyzing, interpreting data (including biological materials)
 - Storage, access & use of biological materials (e.g., DNA & tissue, etc.)
 - Dissemination & publication of research findings

Justice & benefit sharing

Maximize fair benefits & minimise harms

Implementation, periodic evaluation, & refinement

^aUnless culturally inappropriate.

Sources: Reproduced from Association for Canadian Universities of Northern Studies (ACUNS) (2003); Cargo and Mercer (2008); CTSA Community Engagement Key Function Committee Task Force on the Principles of Community Engagement (2011); Lavery *et al.* (2010); Macaulay *et al.* (1999); Minkler and Wallerstein (2008); Presidential Commission for the Study of Bioethical Issues (2011); Ross *et al.* (2010a); UN AIDS (2007) and World Health Organization and Centre for Indigenous Peoples' Nutrition and Environment (2003).

genetic research ethics conflicts, adjudicating associated wrongs and enabling reparations for disrespect of persons and their communities.

Ethical Concepts to Translate 'Respect for Community'

Against the conceptual and historical background sketched above, we turn to ethical processes and structures that help to translate respect for communities in genetics research. Those we identify are not intended to be exhaustive. Rather, these processes and structures illustrate ethics elements and research approaches that enable respect for community. They include the following: collaborative community research; jointly defining research priorities, agenda and questions; free and informed consent; joint interpretation and dissemination of results; community advisory boards and ethics committees; and fair benefit sharing.

Collaborative research: participatory research and community engagement principles

Respect for community is translated by adherence to leading collaborative research principles. For the purposes of this discussion, we define community as "[a] group of people sharing a common interest. Cultural, social, political, health, and/or economic interests link the individuals, who may or may not share a particular geographic association" (Green *et al.*, 1995, p. 3). The relevance of this broad definition for collaborative research is that those most directly affected by the issue being studied (i.e. the community) have particular insights about the problem and its solutions (Green *et al.*, 1995). Thus, in genetic research, depending on the research focus, a community may include a group sharing a common geographic location, ethnicity, disease, occupation, etc. as well as virtual communities linked regionally, nationally or internationally. Collaborative research shifts the focus from doing research on or in a community to conducting research in partnership with a community. The rationales,

Table 3 Selected norms reflective of ‘Respect for Community’: an international sampling (2003–2013)

	Respect for community	Collaborative research ^p	Community/group consent	Community advisory/ethics boards	Fair benefit sharing
Africa (Nigeria ^a and Uganda ^b)			CC	X	X
Australia ^c	X	X	CC	–	X
Canada ^d	X	X	CC ^e	X	X
CIOMS ^f	A ^g	X	C	X	X
India ^h			CC	X	X
New Zealand ⁱ	X	X	CC	–	X
UNESCO			C ^j	X ^k	X ^l
United States ^m		X	CC	X	
WHO ⁿ	X	X	CC	X	X
WMA/Helsinki ^o			C		X

^aNigeria, National Health Research Ethics Committee. *National Code of Health Research Ethics*, 2007.

^bUganda, National Council for Science and Technology. *National Guidelines for Research Involving Humans as Research Participants*, 2007.

^cAustralia, National Statement on Ethical Conduct in Human Research, 2007; Australian Institute of Aboriginal and Torres Strait Islander Studies. *Guidelines for Ethical Research in Australian Indigenous Studies*, 2012.

^dCanadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. (TCPS) 2010, arts 9.1–9.20*. See also, Association of Canadian Universities for Northern Studies (ACUNS). *Ethical Principles for the Conduct of Research in the North*, 2003.

^eACUNS makes explicit reference to consent of the community. TCPS refers mostly to consultation.

^fCouncil for International Organizations of Medical Sciences (CIOMS). *International Ethical Guidelines for Epidemiological Studies*, 2008.

^gCIOMS's 1991 Ethical Guidelines on Epidemiological Studies make explicit reference to respect for the “dignity of the community...” (see Table 1). The 2008 edition makes separate, indirect and relatively ambiguous reference to the dignity of communities and respect of customs (see, e.g. line 2443).

^hIndian Council of Medical Research. *Ethical Guidelines on Biomedical Research on Human Participants*, 2006.

ⁱNew Zealand. National Ethics Advisory Committee. *Ethical Guidelines for Intervention Studies*, 2012; New Zealand, Health Research Council. *Guidelines for Researchers on Health Research Involving Māori*, 2010.

^jUNESCO. *Universal Declaration on Bioethics and Human Rights* 2005, art. 6.

^kUNESCO. International Declaration on Human Genetic Data, 2003, art. 6b. See also, UNESCO, *Universal Declaration on the Human Genome and Human Rights*, 1997.

^lIbid, art. 19.

^mPresidential Commission for the Study of Bioethical Issues. *Moral Science: Protecting Participants in Human Subjects Research*, 2011.

ⁿWorld Health Organization (WHO), Indigenous Peoples & Participatory Research, 2003. See also, WHO, *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*, 2011.

^oWorld Medical Association. *Helsinki Declaration: Ethical Principles for Medical Research Involving Human Subjects*, 2013.

^pSee also Table 1.

Abbreviations: C, consultation; CC, consultation and consent; and A, ambiguous statement.

ethical bases and evolving practice of collaborative research makes it a preferred model for respecting communities in genetic research (Goering *et al.*, 2008; Weijer, 2003).

For decades, collaborative research has found expression in the theory and practice of participatory research. The term participatory research is used here as an umbrella term to include community-based participatory research, participatory action research, action research, etc. (Cargo and Mercer, 2008; Jagosh *et al.*, 2012; Macaulay *et al.*, 1999), especially in the realm of population health (Minkler and Wallerstein, 2008), and more recently in community engagement (CTSA Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, 2011; Lavery *et al.*, 2010; Presidential Commission for the Study of Bioethical Issues, 2011; Ross *et al.*, 2010b). These traditions share rationales, values and principles (Table 2). Both seek to synergise researcher–

community interests, knowledge and skills; respect the autonomy, welfare, values, and cultures of communities; mobilise, build capacity and promote empowerment of the participating community; and protect the community, its individuals and its subgroups (Ross *et al.*, 2010b). In collaborative research, the community is typically represented through a community advisory board (also called advisory committee, steering committee, etc.) that consists of interested community members and/or organisations.

In its most ideal form, collaborative research develops an equitable partnership that cultivates mutual trust and respect, and shares decision making and cogovernance throughout the research process to enhance the relevance, quality and effectiveness of research (Cargo and Mercer, 2008; Jagosh *et al.*, 2012). International and national research ethics guidelines have endorsed collaborative research principles or elements (Table 3), the merits of which apply to genetic research.

With the purported benefits of collaborative genetic research come intrinsic challenges. The partnership model requires sustained commitments and resources. Questions regarding who represents the community, conflict management and evolving issues that arise through the research project demand joint problem-solving and significant time. The elements of collaborative research warrant more standardisation, study and measures and documentation of processes and outcomes. (Jagosh *et al.*, 2012; Lavery *et al.*, 2010). Conceptually, collaborative research would benefit from more coherent, fruitful interaction between the participatory research and community engagement literatures (Table 2).

Jointly defining research priorities, agendas and questions: towards research agreements

Who defines research priorities, agendas and projects?

Implicit in the question is an acknowledgement that research agendas and priorities may be largely developed in academia, in the community or jointly. Collaborative research rejects paternalistic extra-community roles and responsibilities or research that does not adhere to a community's values and its evolving research needs and choices as contrary to respect for community. Because research touches facets of justice (Ross *et al.*, 2010b; Table 2), we agree that academic researchers have a moral responsibility to place community interests at the centre of the research (Goering *et al.*, 2008). Collaborative genetic research should help to define and address community health needs and support community development and self-determination. Three examples of collaborative research with Indigenous peoples in Canada positively illustrate the model in action.

First, in the early 1990s, academic researchers asked a First Nations community in Ontario whether they would be interested in research to document the prevalence, risk factors and genetic basis of type 2 diabetes in their community (Hanley *et al.*, 1995). Based on the long-term relationship with a regional medical director of health (who became the principal investigator of the overall project), the community agreed to participate in genetic testing. The academic–community research team crafted a research agreement that included a clause for sharing any revenue resulting from the overall research (Hegele, personal communication in Parry *et al.*, 2009). The study identified genetic factors that predisposed some First Nations peoples to type 2 diabetes; it also concluded that increasing obesity played a role in the development of the disease, which confirmed the importance of undertaking community healthy lifestyle interventions (Hegele *et al.*, 2003).

Two other examples illustrate the defining of genetic research priorities by First Nations communities in British Columbia. Arbour and Cook (2006) described a case where a community physician recognised a liver disorder within a family. The family and community engaged an external

genetic researcher and together they shaped the research, enabling early, accurate diagnosis and increasing community awareness (Arbour and Cook, 2006). In a parallel case, another Canadian Indigenous community directed initiation of a study and partnered with an academic researcher to frame the research protocol, ethics review and community consent. The collaboration identified a novel mutation of a genetic heart condition, enabling earlier diagnosis and appropriate treatment (Arbour *et al.*, 2008). In this and the foregoing cases, the research partnership yielded new knowledge and community benefits, illustrating the merits of collaborative approaches to genetic research.

Consistent with such cases and the vision of collaborative research outlined in Table 2, when academics propose research questions, they have a duty to engage the community in discussions of the proposed research. Early discussions benefit from initial face-to-face meetings to allow researchers to explain the research purpose, goals and questions in clear, nontechnical, understandable language. This is an opportunity for community members to share their experiences, expertise, cultural values, and concerns. It helps in the joint shaping and refining of research question(s) and the proposed design. Thus, even before consent, community members add their perspectives to ensure genetic research addresses their needs, values and context. This builds on community strengths (e.g. insider knowledge, skills and resources) and advances community research benefits (Jagosh *et al.*, 2012). Discussions should promote maximising fair benefits and minimising harms of individuals, the community and subgroups thereof (Ross *et al.*, 2010b). Unless culturally inappropriate, collaborative research benefits from written agreements outlining the obligations of all partners throughout the process (Parry *et al.*, 2009). The literature offers guidance on developing collaborative research partnerships (Israel *et al.*, 2008; Ross *et al.*, 2010a), research teams (Parry *et al.*, 2009; <http://depts.washington.edu/ccph/>), research agreements (Steinbock, 2007), and checklists for team members to evaluate their level of research involvement (<http://lgreen.net/guidelines.html>).

Free and informed 'consent'

Respect for community is also advanced by the goals, functions and process of free and informed 'consent' for community in addition to individual consent. As with individuals, informed consent with communities in genetic research serves basic goals and genetic-specific functions. These include the following: (1) discussing the purpose, means, uncertainties and desired outcomes of research; (2) partnering to exchange information and knowledge for informed decision making; (3) identifying and disclosing the risks, benefits and alternatives of participation to enable the informed, voluntary assumption and allocation of risks/benefits; (4) protecting bodily, mental, reputational and cultural integrity; (5) specifying the collection and use(s), storage, control and access to biogenetic specimens, like blood and DNA; (6) specifying the sensitive

nature of some genetic information/data and detailing corresponding confidentiality protections (e.g. anonymising, coding, etc.) (UNESCO, 2003); (7) discussing agreement to, limits on, and any re-consent for secondary use of collected materials and data; (8) determining the scope, content and limits of consent; and (9) respecting the dignity, autonomy and self-determination of the community. An effective researcher–community consent process entails foresight, continuing dialogue, and dynamic and purposive application of consent elements in light of evolving research and ongoing ethics analysis.

In recognition of such functions, over the last decade nations and international organisations have incorporated group/community consent into their ethics policies: Guidelines from UNESCO, India, New Zealand, Australia and Canada reference community or group consent (Table 3). India, for instance, indicates a need to undertake ‘group consent from a culturally appropriate authority’ for genetic research in communities (Indian Council of Medical Research, 2006). All regard group consent as an additional ethical step that does not supplant individual informed consent. UNESCO illustrates a standard approach by indicating: “in appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representative of the group or the community concerned may be sought” (UNESCO, 2005).

Despite increased recognition of informed consent of communities, important challenges remain. Terminology is not uniform. Guidelines refer to group consent, community authorisation, permission, approval and community assent (Table 3). Such terms are not synonymous; they often express ethical difference and nuance. Some authors argue ‘consultation’ is more apt when negotiating with widely dispersed communities or with those without an organised structure or governance system (Botkin, 2010); others emphasise that consultation differs from consent (Dickert and Sugarman, 2005). The very process of ‘community consent’ also raises several issues (Schrag, 2006). Who is community and who may legitimately represent it? Do participating community members act as individuals; do they represent the whole community or particular community organisations? Are those from the community but living elsewhere community members? (Israel *et al.*, 2008, p. 53). Do community members trust the process and their representatives? What steps will keep the broader community abreast of the research and accountable to its needs? Answers to such questions may vary depending on the group’s customs, political, cultural and legal governance.

Beyond the community consent process, the specificity, scope and duration of consent remain constant challenges. The challenge is shown in the Havasupai case (Harmon, 2010) and by proposals for ‘broad’ or ‘blanket’ consent for unspecified long-term future research use of banked genetic materials (European Commission, 2012; Hansson *et al.*, 2006). The proposal seems tantamount to a waiver for future re-consent, focuses on individual consent and has

provoked debate (Budimir *et al.*, 2011; Hansson *et al.*, 2006; Hofmann, 2009). It prompts a question: would blanket community consent for genetic research be consistent with the values and workings of respect for community? See also: [Human Genome Diversity Studies: Impact on Indigenous Communities](#)

Community ethics deliberations and review

Community-based ethics deliberations and review of research help to implement respect for communities. At an initial stage of collaborative research, the community reviews proposed research (Table 2). This complements university and institutional research ethics committees (RECs) and provides reflection on potential benefits and harms as perceived by the community.

Community review may occur through an existing political governance structure, a community level research ethics committee or a project-specific community advisory board (CAB). Increasingly, community codes of research ethics exist for individual projects (e.g. Kahnawake Schools Diabetes Prevention Project; www.ksdpp.org/elder/code_ethics.php), groups (e.g. Mi’kmaw; www.cbu.ca/mrc/ethics-watch; Newfoundland and Labrador Health Research Ethics Authority, 2012; World Health Organization and Centre for Indigenous Peoples’ Nutrition and Environment, 2003) and diseases (e.g. human immunodeficiency virus; UN AIDS, 2007).

CABs are standard practice in collaborative research and may convene community stakeholder interests and advance ethical deliberations in genetic research (Simon *et al.*, 2011; Table 2). Under Nigerian research ethics guidelines, CABs “provide community members with an opportunity to share their views about ethical issues that proposed research raises for individual community members, [and] the community as a whole...” (Nigeria National Health Research Ethics Committee, 2007). Honest discussions between researchers and communities offer opportunities for bidirectional learning, increasing community knowledge and awareness and promoting researcher understanding of the cultural and social context. Community ethics review may strengthen research; for, as Foster reported, “research proposals presented for community review were not simply approved or disapproved, previously unforeseen risks were identified and steps taken to minimise potential harms...” (Foster *et al.*, 1999, p. 1723). When a community perceives harms as outweighing benefits, the assessment should be honoured out of respect for community. Unless amendments reshift the balance, the research should not proceed, as it is the community who will live with negative research consequences.

Because community RECs and CABs have complementary mandates that supplement university/institutional RECs, their roles necessitate harmonisation, clarity and ongoing refinement. They illustrate community-based ethics processes created to improve the community–

researcher dialogue (Shore *et al.*, 2011). Optimally, the dialogue enhances understanding, research and mutual respect.

Joint interpretation of results and dissemination, including publication

Joint researcher–community interpretation and dissemination of research results advance respect for community.

This is a key stage in collaborative research that requires ongoing joint decision making. All preliminary findings should first be discussed by the full researcher–community team. Discussion that fosters community members' feedback helps to ensure that results are interpreted in light of community context and knowledge, in addition to academic perspectives. This promotes richer understanding of results and allows discussion about potential risks and harms during external dissemination. Dissemination to maximise knowledge translation should first occur within the community so that research participants and the entire community can benefit from new knowledge and explanation of the findings and be made aware of information to be disseminated externally. External dissemination should include the community contextual information to maximise benefits and minimise harms in case results have a negative impact. Ross *et al.* (2010b) described nine levels of potential harms or 'risks to well-being' to individuals, groups within the community and the entire community. Their examples include individual harm of psychological difficulty for those who tested positive to a genetic predisposition, group harm for those having difficulty acquiring insurance because of belonging to a group with a high risk of disease, and community harm such as the Havasupai tribe where geneticists traced tribal origins as differing from oral history.

Ideally, publications and conference presentations can be coauthored, and at a minimum, community members should be asked to review materials before submission for publication to ensure accuracy in describing the community and the relevant contexts. Respect for community also means that "researchers should seek the consent of the community before speaking to the press about study findings" (Weijer, 2003, p. 2).

Interpreting and publishing results will sometimes test principles of equitable research partnerships. An extreme example might be the threat of a community veto on publishing sensitive research results. If so, what rights and duties prevail? Resolving such conflicts may turn on several questions, including: what perceived ills animate the potential veto – community harms, disagreement on interpretation, communication, text or dissemination? Does the research agreement foresee such risks and outline collaborative steps for research review, (co-)authorship and publication? If such steps still yield disagreement, what dispute resolution process best mediates, minimises or resolves contested points – CAB and REB consultation, a mediator? What is the (mis)understanding on data use, interpretation and 'ownership'? When joint decision

making on residual intractable issues fails to resolve them, what may be unilaterally decided? For instance, some community research ethics codes indicate that no partner can unilaterally veto communications but may include dissenting views in the dissemination of results (Macaulay *et al.*, 1998). The difficulty of managing contested issues near the end of a project explain why we and others recommend proactive negotiation of detailed provisions on publishing protocols, data ownership and dispute resolution in collaborative research agreements (Tri-Council Policy Statement, 2010).

Fair benefits sharing: justice

Genetic research that equitably imparts fair benefits to participating communities advances the principle of respect for communities. National and international ethics policy statements continue to solidify fair benefits as a leading ethical standard in modern human genetics research (Table 3). From its use in international biodiversity law in the 1990s (United Nations, 1993) to its incorporation in ethical guidelines on genetic and scientific research in the 2000s (HUGO Ethics Committee, 2000), benefit sharing is now a standard, best practice and duty. Its emergence has come in response to the question: will the community be harmed; if not, how will it benefit from participation (Ndebele and Musesengwa, 2008)? This touches on the distribution of benefits from participation, the avoidance of exploitation and the furtherance of equity in the research partnership. In short, sharing fair benefits derives from principles of justice (Australia, National Health and Medical Research Council, Australian Research Council, and Australian Vice-Chancellors' Committee, 2007).

The implementation of benefit sharing finds guidance from important considerations in the literature. Context, for instance, helps to shape the meaning of fairness, as a universal definition remains elusive. Actual benefits may range from return of research results (Knoppers *et al.*, 2012) to access to health care or technology, to capacity building (Lairumbi *et al.*, 2012), to developing community infrastructure, like biobanks (HUGO ethics committee, 2000). Because the perception of benefits may depend on cultural and economic lenses (Lairumbi *et al.*, 2011), prior discussion with communities is essential to respecting their needs, autonomous deliberations and equitable partnerships in genetic research. Fair benefits, by definition, must not provide undue inducement to participation (UNESCO, 2005).

Standing Questions and New Challenges

Increased recognition of an ethical principle of respect for community presents challenges. A commitment to the

implementing ethics elements that we have identified – from fair benefits or informed consent of the community to jointly setting research priorities in collaborative research with communities – raises some of the specific issues noted above. As they are confronted and studied and implemented and refined in the coming years, we project that they will do so with fuller recognition of respect for community as both a principle and ethical duty – to be applied in context – in modern human research ethics.

As that future unfolds, we expect that it will more optimally do so by continuing work on standing questions and new challenges:

- In terms of community: what is it; who represents it when there is no legitimate political authority; may a community withdraw consent even if individuals wish to participate; and how should oppressed groups within a community be protected?
- Towards a more coherent understanding of collaborative research: how may researchers and communities, scholars, journal editors, reviewers and publications best standardise, harmonise and apply diverse models of collaborative community research (from community engagement to all forms of participatory research)?
- For biobanking: should communities maintain ownership, access and control (Schnarch, 2004; United Nations, 2008) over banked genetic samples or resulting data, even after the specimens are destroyed in whole genome sequencing; should the samples properly be considered on loan (Arbour and Cook, 2006) or held in trust (Uganda) for the community; should communities enter into profit sharing agreements on genetic research; what constitutes valid consent if future uses of samples/data remain unknown; what are a researcher's responsibilities for return of results (individualised or aggregated); and what are the ethical duties for incidental findings (Arbour and Cook, 2006; Beskow *et al.*, 2012; Dove *et al.*, 2012; Haga and Beskow, 2008; Hens *et al.*, 2013; Hug *et al.*, 2012; McGuire *et al.*, 2008; O'Doherty *et al.*, 2012)? **See also:** [Biobanking: Social, Political and Ethical Aspects; Genetic Information Access, a Legal Perspective: A Duty to Know or a Right Not to Know, and a Duty or Option to Warn?](#)

To inform such issues, we invite theoretical, policy and empirical analyses on these questions and the roles and attitudes of participants and researchers (Goldenberg *et al.*, 2011; Lemke *et al.*, 2010, 2012; O'Doherty *et al.*, 2012; Sharp and Foster, 2000; Simon and Robiński, 2009), on ethics entities (Lemke *et al.*, 2011), and community advisory boards (Lemke *et al.*, 2010), along with innovative public education and engagement initiatives.

Acknowledgment

We acknowledge Participatory Research at McGill for funding Paula Bush PhD and David Parry B.C.L./LL.B.

References

- Arbour L and Cook D (2006) DNA on loan: issues to consider when carrying out genetic research with aboriginal families and communities. *Community Genetics* **9**(3): 153–160. doi: 10.1159/000092651.
- Arbour L, Rezazadeh S, Eldstrom J *et al.* (2008) A KCNQ1 V205M missense mutation causes a high rate of long QT syndrome in a First Nations community of northern British Columbia: a community-based approach to understanding the impact. *Genetics in Medicine* **10**(7): 545–550. doi: 10.1097/GIM.0b013e31817c6b19.
- Association for Canadian Universities of Northern Studies (ACUNS) (2003) *Ethical Principles for the Conduct of Research in the North*. Ottawa, ON. Available at: <http://www.nri.nu.ca/pdf/EthicsEnglishmarch2003.pdf> (accessed on 25 March 2014)
- Beskow LM, Burke W, Fullerton SM *et al.* (2012) Offering aggregate results to participants in genomic research: opportunities and challenges. *Genetics in Medicine* **14**(4): 490–496. doi: 10.1038/gim.2011.62.
- Botkin JR (2010) Informed consent for genetic research. *Current Protocols in Human Genetics*, chap. 1(Suppl. 66), 1.16.11–1.16.13. doi: 10.1002/0471142905.hg0116s47.
- Budimir D, Polasek O, Marusic A *et al.* (2011) Ethical aspects of human biobanks: a systematic review. *Croatian Medical Journal* **52**(3): 262–279.
- Cargo M and Mercer SL (2008) The value and challenges of participatory research: strengthening its practice. *Annual Review of Public Health* **29**(1): 325–350. doi: 10.1146/annurev.publhealth.29.091307.083824.
- CTSA Community Engagement Key Function Committee Task Force on the Principles of Community Engagement (2011) *Principles of Community Engagement (11-7782)*. National Institutes of Health. Available at: http://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf
- Dickert N and Sugarman J (2005) Ethical goals of community consultation in research. *American Journal of Public Health* **95**(7): 1123–1127. doi: 10.2105/ajph.2004.058933.
- Dove ES, Joly Y and Knoppers BM (2012) Power to the people: a wiki-governance model for biobanks. *Genome Biology* **13**(5). doi: 10.1186/gb-2012-13-5-158.
- European Commission (2012) *Biobanks for Europe: A Challenge for Governance*. Luxembourg. Available at: http://www.publichealth.ox.ac.uk/helex/biobanks_for_Europe.pdf
- Foster MW, Sharp RR, Freeman WL *et al.* (1999) The role of community review in evaluating the risks of human genetic variation research. *American Journal of Human Genetics* **64**(6): 1719–1727. doi: 10.1086/302415.
- Goering S, Holland S and Fryer-Edwards K (2008) Transforming genetic research practices with marginalized communities: a case for responsive justice. *Hastings Center Report* **38**(2): 43–53. doi: 10.1353/hcr.2008.0027.
- Goldenberg AJ, Hull SC, Wilfond BS *et al.* (2011) Patient perspectives on group benefits and harms in genetic research. *Public Health Genomics* **14**(3): 135–142. doi: 10.1159/000317497.
- Gostin LO (1991) Ethical principles for the conduct of human subject research: population-based research and ethics. *Law, Medicine & Health Care* **9**: 191–201.

- Greely HT (2001) Human genomics research – New challenges for research ethics. *Perspectives in Biology and Medicine* **44**(2): 221–229. doi: 10.1353/pbm.2001.0026.
- Green LW, George MA, Daniel M *et al.* (1995) *Study of Participatory Research in Health Promotion: Review and Recommendations for the Development of Participatory Research in Health Promotion in Canada*. Ottawa: The Royal Society of Canada.
- Haga SB and Beskow LM (2008) Ethical, legal, and social implications of biobanks for genetics research. In: Rao D and Gu C (eds) *Genetic Dissection of Complex Traits*, 2nd edn, vol. 60, pp. 505–544. San Diego: Academic Press.
- Hanley AJG, Harris SB, Gittelsohn J *et al.* (1995) The Sandy Lake Health and Diabetes Project: design, methods and lessons learned. *Chronic Disease in Canada* **16**(4): 149–155.
- Hansson MG, Dillner J, Bartrarn CR *et al.* (2006) Should donors be allowed to give broad consent to future biobank research? *Lancet Oncology* **7**(3): 266–269. doi: 10.1016/s1470-2045(06)70618-0.
- Harmon A (2010) Indian tribe wins fight to limit research of its DNA. *New York Times*. Available at: http://www.nytimes.com/2010/04/22/us/22dna.html?hpw&_r=0
- Health Research Council of New Zealand (2010) *Guidelines for Researchers on Health Research Involving Māori*. Auckland, New Zealand. Available at: <http://www.hrc.govt.nz>
- Hegele RA, Zinman B, Hanley AJ *et al.* (2003) Genes, environment and Oji-Cree type 2 diabetes. *Clinical Biochemistry* **36**(3): 163–170.
- Hens K, Van El CE, Borry P *et al.* (2013) Developing a policy for paediatric biobanks: principles for good practice. *European Journal of Human Genetics* **21**(1): 2–7. doi: 10.1038/ejhg.2012.99.
- Hofmann B (2009) Broadening consent-and diluting ethics? *Journal of Medical Ethics* **35**(2): 125–129. doi: 10.1136/jme.2008.024851.
- Hug K, Hermeren G and Johansson M (2012) Withdrawal from Biobank Research: considerations and the way forward. *Stem Cell Reviews and Reports* **8**(4): 1056–1065. doi: 10.1007/s12015-012-9399-y.
- HUGO Ethics Committee (2000) Hugo ethics committee statement on benefit sharing April 9, 2000. *Clinical Genetics* **58**(5): 364–366.
- Indian Council of Medical Research (2006) *Ethical Guidelines for Biomedical Research on Human Participants*. New Delhi: Indian Council of Medical Research.
- Israel BA, Schulz A, Parker EA *et al.* (2008) Critical issues in developing and following community based participatory research principles. In: Minkler M and Wallerstein N (eds) *Community-Based Participatory Research for Health*, pp. 47–66. San Francisco: Jossey-Bass.
- Jagosh J, Macaulay AC, Pluye P *et al.* (2012) Uncovering the benefits of participatory research: implications of a realist review for health research and practice. *Milbank Quarterly* **90**(2): 311–346. doi: 10.1111/j.1468-0009.2012.00665.x.
- Jones DJ (2001) *Selected Legal Issues in Genetic Testing: Guidance from Human Rights*. Ottawa. Available at: <http://publications.gc.ca/site/eng/104894/publication.html>
- Knoppers BM, Deschênes M, Ma'n HZ *et al.* (2012) Population studies: return of research results and incidental findings Policy Statement. *European Journal of Human Genetics* **21**(3): 245–247.
- Lairumbi GM, Parker M, Fitzpatrick R *et al.* (2011) Stakeholders understanding of the concept of benefit sharing in health research in Kenya: a qualitative study. *BMC Medical Ethics* **12**: 20. doi: 10.1186/1472-6939-12-20.
- Lairumbi GM, Parker M, Fitzpatrick R *et al.* (2012) Forms of benefit sharing in global health research undertaken in resource poor settings: a qualitative study of stakeholders' views in Kenya. *Philosophy, Ethics, and Humanities in Medicine* **7**(1): 7. doi: 10.1186/1747-5341-7-7.
- Lavery JV, Tinadana PO, Scott TW *et al.* (2010) Towards a framework for community engagement in global health research. *Trends in Parasitology* **26**(6): 279–283. doi: 10.1016/j.pt.2010.02.009.
- Lenke AA, Halverson C and Ross LF (2012) Biobank participation and returning research results: perspectives from a deliberative engagement in South Side Chicago. *American Journal of Medical Genetics Part A* **158A**(5): 1029–1037. doi: 10.1002/ajmg.a.34414.
- Lenke AA, Smith ME, Wolf WA *et al.* (2011) Broad data sharing in genetic research: views of institutional review board professionals. *Irb* **33**(3): 1–5.
- Lenke AA, Wolf WA, Hebert-Beirne J *et al.* (2010) Public and Biobank participant attitudes toward genetic research participation and data sharing. *Public Health Genomics* **13**(6): 368–377. doi: 10.1159/000276767.
- Macaulay AC, Commanda LE, Freeman WL *et al.* (1999) Participatory research maximises community and lay involvement. *British Medical Journal* **319**(7212): 774–778.
- Macaulay AC, Delormier T, McComber AM *et al.* (1998) Participatory research with native community of Kahnawake creates innovative Code of Research Ethics. *Canadian Journal of Public Health* **89**(2): 105–108.
- McGuire AL, Caulfield T and Cho MK (2008) Research ethics and the challenge of whole-genome sequencing. *Nature Reviews Genetics* **9**(2): 152–156.
- Mello MM and Wolf LE (2010) The Havasupai indian tribe case – Lessons for research involving stored biologic samples. *New England Journal of Medicine* **363**: 204–207.
- Minkler M and Wallerstein N (2008) *Community-Based Participatory Research for Health: From Process to Outcomes*, 2nd edn. San Francisco: Jossey-Bass.
- National Bioethics Advisory Commission (1999) *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*. Rockville, MD. Available at: <http://bioethics.georgetown.edu/nbac/hbm.pdf>
- National Health and Medical Research Council, Australian Research Council, and Australian Vice-Chancellors' Committee (2007) *National Statement on Ethical Conduct in Human Research*. Australia: Australian Government. Available at: http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72.pdf
- Ndebele P and Musesengwa R (2008) Will developing countries benefit from their participation in genetics research? *Malawi Medical Journal* **20**(2): 67–69.
- Newfoundland and Labrador Health Research Ethics Authority (2012) *Health Research Ethics Board Policy Manual*. Newfoundland and Labrador: Office of Research Services. Available at: <http://www.hrea.ca/getdoc/df5f8e8a-5501-4f45-ab5f-ca5391562f39/Policy-Manual-March-27-2012-%28LATEST%29.aspx>

- Newfoundland and Labrador, Health Research Ethics Authority Regulations, Regulation 57/11 (2011). Available at: <http://www.assembly.nl.ca/legislation/sr/regulations/rc110057.htm> (accessed on 25 March 2014).
- Nigeria National Health Research Ethics Committee (2007) *National Code for Health Research Ethics of the Federal Republic of Nigeria*. Available at: <http://www.nhrec.net>
- O'Doherty KC, Hawkins AK and Burgess MM (2012) Involving citizens in the ethics of biobank research: informing institutional policy through structured public deliberation. *Social Science & Medicine* **75**(9): 1604–1611. doi: 10.1016/j.socscimed.2012.06.026.
- Parry D, Salsberg J and Macaulay AC (2009) *Guide to Researcher and Knowledge-User Collaboration in Health Research*, pp. 1–83). Ottawa: Canadian Institutes of Health Research (CIHR). Available at: <http://www.cihr-irsc.gc.ca/e/44954.html>
- Presidential Commission for the Study of Bioethical Issues (2011) *Moral Science: Protecting Participants in Human Subjects Research*. Available at: <http://bioethics.gov/node/558>
- Pullman D (2005) Research governance, bio-politics and political will: recent lessons from Newfoundland and Labrador. *Health Law Review* **13**(2–3): 75–79.
- Rahman P, Jones A, Curtis J *et al.* (2003) The Newfoundland population: a unique resource for genetic investigation of complex diseases. *Human Molecular Genetics* **12**(Suppl. 2): R167–R172. doi: 10.1093/hmg/ddg257.
- Ross LF, Loup A, Nelson RM *et al.* (2010a) Nine key functions for a human subjects protection program for community-engaged research: points to consider. *Journal of Empirical Research on Human Research Ethics* **5**(1): 33–47. doi: 10.1525/jer.2010.5.1.33.
- Ross LF, Loup A, Nelson RM *et al.* (2010b) Human subjects protections in community-engaged research: a research ethics framework. *Journal of Empirical Research on Human Research Ethics* **5**(1): 5–17.
- Santos L (2008) Genetic research in native communities. *Progress in Community Health Partnerships: Research, Education and Action* **2**(4): 321–327. doi: 10.1353/cpr.0.0046.
- Schnarch B (2004) Ownership, control, access, and possession (OCAP) or self-determination applied to research. *Journal of Aboriginal Health* **1**(1): 81.
- Schrag B (2006) Research with groups: group rights, group consent, and collaborative research. *Science and Engineering Ethics* **12**(3): 511–521.
- Sharp RR and Foster M (2000) Involving study populations in the review of genetic research. *Journal of Law Medicine & Ethics* **28**(1). doi: 10.1111/j.1748-720X.2000.tb00315.x.
- Shore N, Brazauskas R, Drew E *et al.* (2011) Understanding community-based processes for research ethics review: a national study. *American Journal of Public Health* **101**: S1. doi: 10.2105/AJPH.2010.194340.
- Simon CM, Newbury E and L'Heureux J (2011) Protecting participants, promoting progress: public perspectives on community advisory boards (CABs) in biobanking. *Journal of Empirical Research on Human Research Ethics* **6**(3): 19–30. doi: 10.1525/jer.2011.6.3.19.
- Simon J and Robiński J (2009) Property, personality rights and data protection with regard to biobanks – A layered system. *International Journal of Bioethics* **20**(3): 47–56.
- Steinbock MB (2007) How to draft a collaborative research agreement. In: Krattiger A, Mahoney RT, Nelsen L *et al.* (eds) *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, pp. 717–724. Oxford, UK: MIHR, Davis, USA: PIPRA, Fiocruz, Rio de Janeiro, Brazil: Oswaldo Cruz Foundation and Ithaca, USA: bio Developments-International Institute. Available at: www.ipHandbook.org
- The Nuremberg Code (1996) The Nuremberg Code 1947. *British Medical Journal* **313**(7070): 1448. doi: 10.1136/bmj.313.7070.1448.
- Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (2010) chap. 9.1. Available at: http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf
- UN AIDS (2007) The greater involvement of people living with HIV (GIPA): policy brief. Available at: http://data.unaids.org/pub/Report/2007/JC1299-PolicyBrief-GIPA_en.pdf
- UNESCO (2003) *International Declaration on Human Genetic Data*. Paris, France: United Nations Educational, Scientific, and Cultural Organization (UNESCO).
- UNESCO (2005) *Universal declaration on bioethics and human rights*. Adopted at the 33rd Session of the UNESCO General Conference 19 Oct 2005.
- United Nations (1993) *Convention on Biological Diversity*. Rio de Janeiro: United Nations. Available at: <http://www.cbd.int/convention/text/>
- United Nations (2008) *United Nations Declaration on the Rights of Indigenous Peoples*. Available at: http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf
- Weijer C (2003) Community consent for genetic research. *Nature Encyclopedia of the Human Genome* 871–874. Reprinted in: *Encyclopedia of Life Sciences*. doi: 10.1038/npg.els.0005179.
- Widdows H (2009) Between the individual and the community: the impact of genetics on ethical models. *New Genetics and Society* **28**(2): 173–188. doi: 10.1080/14636770902901611.
- World Health Organization and Centre for Indigenous Peoples' Nutrition and Environment (2003) *Indigenous Peoples' and Participatory Health Research: Planning and Management/Preparing Research Agreements*. Geneva: World Health Organization. Available at: http://www.who.int/ethics/indigenous_peoples/en/index6.html

Further Reading

- Castellano Brant M and Reading J (2010) Policy writing as dialogue: drafting an Aboriginal chapter for Canada's tri-council policy statement: ethical conduct for research involving humans. *International Indigenous Policy Journal* **1**(2): 1–18.
- Duran E and Duran B (1995) *Native American Postcolonial Psychology*. Albany: State University of New York Press.
- Freeman W (1998) The protection of potential individual volunteers and tribal communities in research involving the Indian health services. *US Indian Health Services Institutional Research Board Appendix*, pp. 77–78. Available at: http://www.npaihb.org/images/epicenter_docs/irb/docs/Protections_fr.pdf
- Israel BA (2013) *Methods for Community-Based Participatory Research for Health*, 2nd edn. San Francisco: Jossey-Bass.

- Israel BA, Schulz AJ, Parker EA *et al.* (1998) Review of community-based research: assessing partnership approaches to improve public health. *Annual Review of Public Health* **19**: 173–202. doi: 10.1146/annurev.publhealth.19.1.173.
- Minkler M and Wallerstein N (2008) *Community-Based Participatory Research for Health: From Process to Outcomes*, 2nd edn. San Francisco, CA: Jossey-Bass.
- Skloot R (2010) *The Immortal Life of Henrietta Lacks*, 1st edn. New York: Crown Publishers.
- Solbakk JH (2011) In the ruins of Babel: pitfalls on the way toward a universal language for research ethics and benefit sharing. *Cambridge Quarterly of Healthcare Ethics* **20**(3): 341–355. doi: 10.1017/S096318011100003X.
- Tindana PO, Singh JA, Tracy CS *et al.* (2007) Grand challenges in global health: Community engagement in research in developing countries. *Plos Medicine* **4**(9): 1451–1455. doi: 10.1371/journal.pmed.0040273.
- Tsosie R and McGregor JL (2007) Genomic justice: genetics and group rights *Journal of Law & Medical Ethics* **35**(3): 352–456.

Web Link

HumGen/PopGen database: <http://www.popgen.info/database-laws-policies#box-A-C>