Beyond Consent: Respect for Community in Genetic Research

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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 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.
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 1946; 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

<table>
<thead>
<tr>
<th>Rationales</th>
<th>Principles</th>
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<tbody>
<tr>
<td>1. Respects rights, welfare, values, culture and peoples</td>
<td>Mutual respect</td>
</tr>
<tr>
<td>2. Builds effective relationships</td>
<td>Encourages respect &amp; collaboration between researchers &amp; communities</td>
</tr>
<tr>
<td>3. Recognises and nurtures complementary researcher–community knowledge – views, interests, ideas, experience and expertise</td>
<td>Duty to engage</td>
</tr>
<tr>
<td>4. Enhances relevance, quality and uptake of research</td>
<td>Researcher engages community across the continuum of research collaboration: from dialogue &amp; consultation, to authorization, to negotiated research partnership agreements</td>
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<td>5. Mobilises community understanding, involvement and assets</td>
<td>Equitable research partnership</td>
</tr>
<tr>
<td>6. Jointly identifies and manages risks; maximises opportunities and benefits</td>
<td>Shared decision-making and co-governance of the research process</td>
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<tr>
<td>7. Promotes self-determination, empowerment and protection of communities</td>
<td>● Developing written guiding principles/codes of research ethicsa</td>
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<tr>
<td></td>
<td>● Shared design &amp; conduct of research</td>
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<tr>
<td></td>
<td>○ Setting research agenda(s), purpose, goals &amp; questions</td>
</tr>
<tr>
<td></td>
<td>○ Institutional and community ethics review of proposed research</td>
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<tr>
<td></td>
<td>○ Collecting, analyzing, interpreting data (including biological materials)</td>
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<td></td>
<td>○ Storage, access &amp; use of biological materials (e.g., DNA &amp; tissue, etc.)</td>
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<td></td>
<td>○ Dissemination &amp; publication of research findings</td>
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<tr>
<td></td>
<td>Justice &amp; benefit sharing</td>
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<tr>
<td></td>
<td>Maximize fair benefits &amp; minimise harms</td>
</tr>
<tr>
<td></td>
<td>Implementation, periodic evaluation, &amp; refinement</td>
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</tbody>
</table>

*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)

<table>
<thead>
<tr>
<th>Region/Institution</th>
<th>Respect for community</th>
<th>Collaborative research</th>
<th>Community/group consent</th>
<th>Community advisory/ethics boards</th>
<th>Fair benefit sharing</th>
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</thead>
<tbody>
<tr>
<td>Africa (Nigeria and Uganda)</td>
<td></td>
<td></td>
<td>CC</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Australia</td>
<td>X</td>
<td>X</td>
<td>CC</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Canada</td>
<td>X</td>
<td>X</td>
<td>CC</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CIOMS</td>
<td>A</td>
<td>X</td>
<td>C</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>India</td>
<td>X</td>
<td>X</td>
<td>CC</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>New Zealand</td>
<td>X</td>
<td>X</td>
<td>CC</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>UNESCO</td>
<td>X</td>
<td>X</td>
<td>CC</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>United States</td>
<td>X</td>
<td>X</td>
<td>CC</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>WHO</td>
<td>X</td>
<td>X</td>
<td>CC</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>WMA/Helsinki</td>
<td>X</td>
<td>X</td>
<td>C</td>
<td>–</td>
<td>–</td>
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</table>

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

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 measurements 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 reconsent 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 reconsent, 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—
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 (Ndibele 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 Robienski, 2009), on ethics entities (Lemke et al., 2011), and community advisory boards (Lemke et al., 2010), along with innovative public education and engagement initiatives.

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References


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Hansson MG, Dillner J, Bartram 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.


Further Reading


**Web Link**

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