Incidental Findings in Genetic Research: A Vexing Challenge for Community Consent

Elana Brief, Jennifer Mackie, Judy Illes*

INTRODUCTION

An incidental finding is a finding "concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting the research but is beyond the aims of the study."[1] In a genetic family study, for example, a researcher may identify misattributed parentage of a study participant.[2] Or, while surveying the genetic variation of a specific population for one disease (e.g., diabetes), a researcher may find an allelic variation in some individuals that puts them at risk for a different disease than the one under investigation (e.g., cardiovascular dis-

* Judy Illes is the Canada Research Chair in Neuroethics in the Department of Medicine at the University of British Columbia. The authors wish to specially thank Dr. Lynn Beattie for her collaboration and leadership. This work was directly supported by grants from the CIHR Institute of Aboriginal Peoples Health (# MOP-111240), the Vancouver Foundation (# UN-R10-0748), and the North Growth Foundation. Support from the Canadian Dementia Knowledge Translation Network (CDKTN) (CIHR DIP #87302) is also gratefully acknowledged. Work related to this paper at the National Core of Neuroethics at the University of British Columbia is also supported by CIHR (CNE #85117), the British Columbia Knowledge Development Fund, and the Canadian Foundation for Innovation. Preparation of this article was supported in part by the National Institutes of Health (NIH), National Human Genome Research Institute (NHGRI) grant #2-R01-HG003178 on "Managing Incidental Findings and Research Results in Genomic Biobanks & Archives" (Wolf, PI; Kahn, Lawrenz, Van Ness, Co-Is). The contents of this article are solely the responsibility of the author(s) and do not necessarily represent the views of NIH or NHGRI.

1. Susan M. Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED & ETHICS 219, 219 (2008).

2. *Id.* Incidental findings are present in both the course of research and clinical care. *Id.*

ease). By their nature, incidental findings cannot be predicted.[3] For the most part, the clinical significance of a finding may be unclear or negligible; however, some findings may necessitate follow-up clinical consultation.[4] The bulk of the literature on incidental findings considers the ethical implications for an individual research participant,[5] and provides guidance on creating a consent process that incorporates the potential for unanticipated findings.[6] The literature also describes the ethical and logistical complexity of delivering the information of the findings back to the individual research participant.[7] In this paper we explore the issues that emerge when an individual participates in research as a member of a socially-identifiable population that has, as a community, consented to the research. In particular, we consider the implications for community consent surrounding individual incidental findings and focus on three main questions:

Upholding confidentiality: Is it possible to maintain individual confidentiality in a rural or remote community, and if not, how can research be conducted ethically if confidentiality is desired?

Rights of other community members: If others in the community will be affected by the incidental finding (e.g., extended biological family members), do they have a right to knowledge of the results?

Rights of community agencies: If agencies in the community will be affected (e.g., through re-aligning health care priorities), do those organizations have a right to knowledge of the results?

International research ethics guidelines state that indigenous peoples own the results of research conducted with them.[8]

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3. *Id.* ("This means that IFs may be on variables not directly under study and may not be anticipated in the research protocol.").

4. *E.g.*, *id.* at 224 ("IFs are classified as needing immediate referral, urgent referral, routine referral, or no referral.").

5. *See, e.g.*, *id.* at 227–33.

6. *See, e.g.*, *id.* at 233–42.

7. *See, e.g.*, *id.* at 242–43.

8. Grant Gillett & Felicity McKergow, *Genes, Ownership, and Indigenous Reality*, 65 SOC. SCI. & MED. 2093, 2098 (2007) ("The growing world-wide recognition of indigenous rights shown in statements such as the UN Declaration on the Rights of Indigenous Peoples . . . means that indigenous groups are accorded 'the right to full ownership, control and protection of their cultural and intellectual property.'"); s*ee also* Marlene Brant Castellano, *Ethics of Abo-*

How might these guidelines apply to individual incidental findings? Individual ownership of genes is based on Western ideas of individualized property.[9] How can researchers uphold the Western ethical standard of privacy of individual medical information and simultaneously honor cultural values and pragmatic considerations that may be in conflict with those standards?[10] Within an indigenous research context, when might community members and community agencies have rights to individual findings? We suggest that many ethical issues can be addressed by involving community members in guiding a research study.

I. RESEARCHER RESPONSIBILITY TO INDIVIDUALS, COMMUNITIES AND COMMUNITY AGENCIES

There is a growing literature regarding the responsibility of a researcher to notify study participants of incidental findings ("return of results") in genetics research. Shalowitz and Miller argue for full disclosure (i.e., return all results to the individual) based on the Belmont principle of respect for persons.[11] In contrast, Beskow et al. recommend restricted disclosure if, and only if, the results are clinically relevant.[12] Forsberg et al. advocate for no return of results in the case of donated tissue because of the risk of therapeutic misconcep-

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riginal Research, J. ABORIGINAL HEALTH, Jan. 2004, at 98, 109–10 ("Of particular interest for this discussion of research ethics are the principles . . . set out by the RHS Steering Committee . . . [which] assert: collective ownership by First Nations communities of information about themselves and their members . . . .").

9. LINDA TUHIWAI SMITH, DECOLONIZING METHODOLOGIES: RESEARCH AND INDIGENOUS PEOPLES 118 (1999) ("[L]egal definitions of ethics are framed in ways which contain the Western sense of the individual and of individualized property . . . ."); Gillett & McKergow, *supra* note 8, at 2098 (noting that Western notions are based on individual rights and contracts which make property alienable).

10. *See* Gillett & McKergow, *supra* note 8, at 2098 ("Is what is at stake here a question of property at all?").

11. David I. Shalowitz & Franklin G. Miller, *Disclosing Individual Results of Clinical Research: Implications of Respect for Participants*, 294 JAMA 737, 738 (2005).

12. Laura M. Beskow et al., *Informed Consent for Population-Based Research Involving Genetics*, 286 JAMA 2315, 2319–20 (2001) ("We believe that a reasonable means of addressing these dilemmas may be to apply the criterion proposed here: an assessment at the beginning of a research project of the likelihood that the results will generate information that could lead directly to an evidence-based intervention.").

tion.[13] These authors also argue that research funds should only be used for research and not on clinical care.[14] In the case of incidental findings from the use of archived DNA held in a biobank, Clayton outlines the ethical complexities of contacting individuals who may not even be aware that their tissues have been used in secondary analysis.[15] In parallel literature on neuroimaging, Illes et al. have argued that the research protocols should prepare for the possibility of incidental findings upfront and that transparent plans for managing them should be articulated both to review boards and, during the consent process, to prospective participants.[16] These authors have shown that participants would prefer to be informed of anomalies detected in the brain, regardless of their significance or potential actionability.[17]

Most discussions on the return of incidental findings to date are based on the idea that genetic, brain, and other physiologic and biologic data are personal property. Arguments for and against return of results adhere to Western ethical frameworks focused on individual rights (e.g., Belmont Report, Beauchamp & Childress). A necessary literature is emerging on designing adequate individual consent processes to determine whether and how to return incidental findings in primary and

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13. Joanna Stjernschantz Forsberg et al., *Changing Perspectives in Biobank Research: From Individual Rights to Concerns about Public Health Regarding the Return of Results*, 17 EUR. J. HUM. GENETICS 1544, 1546–47 (2009) ("Not acknowledging the difference between research and clinical care is the basis of the therapeutic misconception, which is characterized by individuals wrongfully attributing research the goal (at least in part) of benefiting the research subjects individually.").

14. *Id.* at 1545.

15. Ellen Wright Clayton et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 JAMA 1786, 1788 (1995) ("The ethical dilemma is that it is at best disingenuous and at worst deceptive for the clinician to obtain clinical samples knowing that they are likely to be used for research without mentioning this possibility to the patient.").

16. Judy Illes et al., *Incidental Findings in Brain Imaging Research*, 311 SCI. 783, 783 (2006) ("We believe that all investigators engaged in brain imaging research should anticipate incidental finding in their experimental protocols and establish a pathway for handling them."); *see also* J. Illes et al., *Practical Approaches to Incidental Findings in Brain Imaging Research*, 70 NEUROLOGY 384, 387 (2008) ("It is important that information about resources and procedures for following up are made available to the subject.").

17. Matthew P. Kirschen, Agnieszka Jaworska & Judy Illes, *Subjects' Expectations in Neuroimaging Research*, 23 J. MAGNETIC RESONANCE IMAGING 205, 207 (2006).

secondary research with archived tissue (see, for example, other articles in this issue).[18] To our knowledge, discussion about the potential *communal* effect of the return of results of individual incidental genetic findings in socially-identifiable populations is still absent from the discourse. Consequently, there are no guidelines about how a communal consent process could be designed with respect to incidental findings.

It has only been since the 1990s that national (notably in Australia, Canada, and the United States) and international guidelines have been created to extend research protections to communities.[19] In population-based genetic research with identifiable communities, the risk of group harm, which is distinct from the risk of individual harm, has been clearly documented.[20] At the most basic level, identifying a socially-distinct study population in public databases or scientific publications, which is standard practice, could put all people in that community at risk for discrimination regardless of whether they were study participants.[21] Sharp and Foster specify that there can be two sorts of harm to a community in this regard: tangible and dignitary.[22] Examples of tangible harms are discrimination and stigmatization.[23] Dignitary harms involve "violations of collective rights or disrespectful treatment of the affected community."[24] An example of dignitary harm would be the handling of

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18. *See generally* A.A. Lemke et al., *Public and Biobank Participant Attitudes Toward Genetic Research Participation and Data Sharing*, 13 PUB. HEALTH GENOMICS 368, 374–75 (2010) (discussing a study on attitudes and opinions of research participants).

19. Charles Weijer et al., Commentary, *Protecting Communities in Research: Current Guidelines and Limits of Extrapolation*, 23 NATURE GENETICS 275, 275–77 (1999) (detailing how research guidelines for community protections have been shaped by aboriginal peoples, particularly in countries with significant indigenous populations); *see also* Bette Jacobs et al., *Bridging the Divide Between Genomic Science and Indigenous Peoples*, 38 J.L. MED. & ETHICS 684, 686–88 (2010) (explaining the relationship outlined by the Canadian Institutes of Health Research Guidelines for Health Research Involving Aboriginal People).

20. Sandra Crouse Quinn, *Protecting Human Subjects: The Role of Community Advisory Boards*, 94 AM. J. PUB. HEALTH 918, 918–19 (2004).

21. *Id.* ("With a growing concern about the potential for discrimination, stigmatization, and breaches of privacy in genetic research, participants raised key questions about how community may be defined in research . . . .").

22. Richard R. Sharp & Morris W. Foster, *Community Involvement in the Ethical Review of Genetic Research: Lessons from American Indian and Alaska Native Populations*, ENVTL. HEALTH PERSPS., Apr. 2002 Supp., at 145, 147.

23. *Id.*

24. *Id.*

collected biological materials in a manner that violated community protocols to preserve the sacredness of tissues.[25] This harm extends beyond the individual and would affect the entire community.[26] Individual consent for research participation is not adequate to protect a community. For socially identifiable communities, therefore, national and international guidelines are increasingly recommending the adoption of a participatory, community-based research model in which members of a community are involved in the entire research process from inception to dissemination.[27] Community involvement through a participatory process[28] is seen as the best way to incorporate the community's interests, priorities, and protection into the research.

In this article we focus on community consent for return of incidental findings from genetic research with indigenous peoples; however, many of our ideas can be extended to other socially identifiable populations (e.g., Amish people) and applied beyond genetic research (e.g., incidental findings in imaging studies). We propose, most critically, the engagement of researchers with communities to define, *a priori*, to whom incidental findings belong and to whom results should be returned, and processes for fulfilling this commitment before the biomedical research is ever initiated. We further consider the importance of incorporating individual and communal values to determine the threshold of clinical significance for the incidental findings to be returned and the need to preserve the privacy of individual health information.

II. HISTORICAL BACKGROUND FOR GENETIC RESEARCH AND INDIGENOUS PEOPLES

Genetic research with indigenous peoples has a shameful history. Researchers have handled tissue samples in inappro-

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25. *See id.* ("For example, using stored biological materials in a manner that the community would find morally objectionable can constitute a dignitary harm not only to the individuals who contributed those materials but to the community as a whole.").

26. *Id.*

27. *E.g.*, COLLEEN REID ET AL., OUR COMMON GROUND: CULTIVATING WOMEN'S HEALTH THROUGH COMMUNITY BASED RESEARCH 22 (2009).

28. Kathleen Cranley Glass & Joseph Kaufert, *Research Ethics Review and Aboriginal Community Values: Can the Two Be Reconciled?*, J. EMPIRICAL RES. ON HUM. RES. ETHICS, June 2007, at 25, 28–29.

priate and offensive ways, including using tissues in secondary research without individual or community consent.[29] First Nations and Native American tribes have successfully fought to repatriate their tissues to put an end to research with their DNA.[30] Researchers have also contributed to racist beliefs and perpetuated negative stereotypes through a lack of care in publishing their data.[31] In 2006, for example, Rod Lea et al. presented their findings on ethnic differences in frequencies of a MAO-A allele, dubbed the "warrior gene."[32] These findings fueled a reductionist racial stereotype on aggression and criminality in Maori men that made it possible to overlook the influence of poverty and marginalization on behavior and ignore the historical trauma of colonization.[33] Indigenous peoples worldwide have refused to be part of the Human Genome Diversity Project (HGDP) and the International HapMap Project for many reasons, including their opposition to the ownership of genetic samples, the patentability of the information, and the question of informed consent.[34] In addition, indigenous peoples were frustrated by the research justification: that knowledge gained through the HGDP project would be used to benefit all people. Historically, Western health research has been largely

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29. *See*, *e.g.*,. Laura Arbour & Doris Cook, *DNA on Loan: Issues to Consider When Carrying Out Genetic Research with Aboriginal Families and Communities*, 9 COMMUNITY GENETICS 153, 153–54 (2006) (describing how blood entrusted to researchers by a First Nation for medical research reasons was instead used to establish ancestry without their knowledge or consent).

30. *See* LorrieAnn Santos, *Genetic Research in Native Communities*, 2 PROGRESS COMMUNITY HEALTH PARTNERSHIPS: RES., EDU., & ACTION 321, 322 (2008) (detailing how Native American tribes, such as the Havasupai of Arizona, have sought legal action against academics who abused their privileges as researchers). *See generally* Arbour & Cook, *supra* note 29, at 154 (outlining processes to ensure that genetic research with Canadian First Nations is respectful).

31. *See* SMITH, *supra* note 9, *passim*.

32. *E.g.*, Paul Chapman, *Violence Is Blamed on "Warrior Gene" in the Maoris*, DAILY TELEGRAPH (U.K.), Aug. 10, 2006, at 019.

33. *But cf.* Rod Lea & Geoffrey Chambers, *Monoamine Oxidase, Addiction, and the "Warrior" Gene Hypothesis*, 120 N. Z. MED.NEW ZEALAND MEDICAL J., Mar, 2, 2007, at 1, http://journal.nzma.org.nz/journal/120-1250/2441/content.pdf. (defending the scientific rationale behind the "warrior gene" hypothesis).

34. Ikechi Mgbeoji, *Talking Past Each Other: Genetic Testing and Indigenous Populations*, ACTION BIOSCIENCE (Sept. 2007), http://www.actionbioscience.org/genomic/mgbeoji.html ("The failure of the HGDP to achieve its target may be attributed to the vociferous opposition of indigenous groups, inspired by the perceived historical injustice to and exploitation of indigenous populations.").

unsuccessful in benefiting indigenous peoples.[35] On a deeper level, indigenous peoples recognized that population genetics has the potential to confirm or refute ancestral origins and may undermine a people's self-determination by imposing an external origin narrative. Genetic ancestral origin information can thus be used to political ends. In Taiwan, for example, research into historic migrations of Taiwan Aborigines has been used to support the replacement of a "One China" ideology with a Taiwan-centered identity.[36] Generally, indigenous peoples have not been the beneficiaries of research—socially, medically, or economically—even though the United Nations Declaration on the Rights of Indigenous Peoples provides them with the rights to their genetic resources.[37]

III. IMPORTANCE OF COMMUNITY PARTICIPATION IN RESEARCH

Putting aside questions on incidental findings, there is clearly a need to conduct genetic research with indigenous peoples more ethically than in the past. Jacobs et al. evaluated international guidelines for genetic research with Indigenous populations for the inclusion of five principles and fifteen subprinciples in the development and execution of a study.[38] The five principles were: "[1] community consultation, [2] sample collection and informed consent, [3] use and storage of biological materials, [4] prioritization of research uses, and [5] post-research obligations."[39] Almost all the guidelines included the need for a discussion of the potential communal harm as part of the individual informed consent process.[40] The guidelines from the Canadian Institutes of Health Research (CIHR) are noted for their recognition that community consent often precedes individual consent in research with Aboriginal peoples.[41] Only

35. *See* SMITH, *supra* note 9, at 2.

36. Mark Munsterhjelm & Frederic Gilbert, *How Do Researcher Duties Conflict with Aboriginal Rights?: Genetics Research and Biobank Problems in Taiwan*, 4 DILEMATA 33, 39–40 (2010).

37. *See* Declaration on the Rights of Indigenous Peoples, G.A. Res. 61/295, U.N. Doc. A/RES/61/295, at 31 (Sept. 13, 2007) ("Indigenous peoples have the right to maintain, control, protect and develop their . . . human and genetic resources . . . .").

38. Jacobs et al., *supra* note 19, at 686.

39. *Id.*

40. *Id.* at 687.

41. *CIHR Guidelines for Health Research Involving Aboriginal People*,

half of the guidelines examined by Jacob et al. required community approval for research.[42]

The unpredictable nature of incidental findings in genetic research complicates the individual and community consent process. Additionally, findings are expressed in terms of probabilities for clinical significance and require deeper explanation about risk. Ethical research with indigenous peoples requires community participation. The representatives of a community would therefore have to be familiar with the nature of genetic research to speak on behalf of their community. Capacity building is an important part of participatory research. To create a balanced dialogue with community members, the academic or clinical researchers should be prepared to teach some of the fundamental ideas of genetic research and to learn what information community members may require to make informed decisions about the research.

A. WHO SPEAKS FOR A COMMUNITY?

Acknowledgement of the role of community involvement in research brings up questions centered around who speaks for a community. The definition or concept of "community" itself is complex. The Royal Commission on Aboriginal Peoples uses the term "community," as in "First Nation community," to refer to:

> [A] relatively small group of Aboriginal people residing in a single locality and forming part of a larger Aboriginal nation or people. Despite the name, a First Nation community would not normally constitute an Aboriginal nation . . . . Rather, most (but not all) Aboriginal nations are composed of a number of communities.[43]

It may seem suitable to simply seek approval for research from the established governing bodies that oversee the Nation. Any indigenous group that has negotiated land claims, land use, or health care has had to resolve questions about group representation. Political representatives, however, may not be the correct people for consultation regarding the implications of genetic research and offering informed consent. Representatives from individual communities within the Nation may have

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CAN. INSTS. HEALTH RES., http://www.cihr-irsc.gc.ca/e/29134.html (last visited Mar. 28, 2012) ("A researcher who proposes to carry out research that touches on traditional or sacred knowledge of an Aboriginal community . . . should consult the community leaders to obtain their consent before approaching community members individually.").

42. Jacobs et al., *supra* note 19, at 687.

43. CANADIAN ROYAL COMM'N ON ABORIGINAL PEOPLES, 5 REPORT OF THE ROYAL COMMISSION ON ABORIGINAL PEOPLES: RENEWAL, at viii (1996).

different perspectives on the potential harms or benefits of the research.

Burgess and Tansey conducted a focus group with Aboriginal participants on the potential benefits and risks of biobanking their genetic materials.[44] Participants were clear that they were not representing their communities, only themselves.[45] After learning more about what biobanking entailed, participants stated the necessity of consulting Elders and deliberating on issues that concerned collective risk.[46] In the context of their genetic research with an Apache community, Foster et al. described a process of identifying public and private social units within the community that are most likely to be consulted on issues of well-being.[47] These groups were deemed to be the correct entities to consult about the implications of genetic research.[48] As Foster et al. demonstrated, research is needed up front to determine who can best represent the community on questions of genetic research. Once identified, a formal entity, like a Community Advisory Board (CAB), can then be brought together to consult with researchers throughout the project.

Sandra Crouse Quinn described the role of a CAB in guiding research to protect community interests.[49] She outlined five responsibilities:

> They can (1) act as a liaison between researchers and community, (2) represent community concerns and culture to researchers, (3) assist in the development of study materials, (4) advocate for the rights of minority research study subjects, and (5) consult with potential study participants to provide recommendations about research study enrollment.[50]

A CAB could thus play a complementary role to the researcher's institutional review board. The CAB could provide

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44. Michael Burgess & James Tansey, *Cultural Authority of Informed Consent: Indigenous Participation in Biobanking and Salmon Genomics Focus Groups*, *in* THE LIMITS OF CONSENT: A SOCIO-ETHICAL APPROACH TO HUMAN SUBJECT RESEARCH IN MEDICINE 199, 202 (Oonagh Corrigan et al. eds., 2009).

45. *Id.* at 204–05.

46. *Id.* at 206–07.

47. Morris W. Foster et al., *The Role of Community Review in Evaluating the Risks of Human Genetic Variation Research*, 64 AM. J. HUM. GENETICS 1719, 1720–1722 (1999).

48. *Id.*

49. Quinn, *supra* note 20, at 920.

50. *Id.*

continuous feedback on the research and guide researchers at every stage of the research process—from design to dissemination. Community members could raise questions around genetic research with the CAB and, with the CAB's support, appropriate individual and communal informed consent processes could be created.

The members of the CAB may be identified by the Indigenous community and selected for their ability to be stewards of Indigenous knowledge. As well, each member of the CAB should have, or be granted, the time to deal with the ethical considerations of the research. The implications of genetic research from the Indigenous community's perspective require time for thoughtful discussion with Elders and others from the Nation. The process for ethical considerations of research in an Indigenous community is analogous to that taken by an institutional review board that seeks to protect both the interests of the institution and the research participants. The members of a CAB or an advisory committee in an Indigenous community are responsible for the protection of the interests of the community and the individuals in it.[51] Members of a CAB should therefore be chosen by the community as their representatives and be given adequate information and time to reflect on the potential implications of the research.

IV. PRIMARY RESEARCH AND INCIDENTAL FINDINGS

Below we outline some of the issues related to return of results and incidental findings in the context of research where individuals and their community have consented to their tissues being used for a specific research question. We are not referring to tissues that have been personally donated to research or clinical samples that have been anonymized and banked.

A. PERSONAL PROPERTY OR COLLECTIVE INHERITANCE

Many specific concerns may emerge in the context of incidental findings from genetic research in an Indigenous community. Some communities may not view genes as personal property, but as cultural heritage[52] or collective inheritance,[53] which

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51. MARGARET KOVACH, INDIGENOUS METHODOLOGIES: CHARACTERISTICS, CONVERSATIONS, AND CONTEXTS 49 (2009).

52. Debra Harry & Le'a Malia Kanehe, *Asserting Tribal Sovereignty over Cultural Property: Moving Towards Protection of Genetic Material and Indigenous Knowledge*, 5 SEATTLE J. FOR SOC. JUST. 27, 31 (2006).

cannot be shared without group consent. If the primary intent of the research is to study a disease or condition for which the entire community is seemingly at risk, there is little conflict between the concepts of personal property or collective stewardship. Incidental findings, however, are defined in terms of the individual and the process of returning results to an individual stems from the Western idea of genes being personal property. A genetic finding, however, connects people to their extended family. In a geographically isolated location, the extended family is supported by its larger community and the health institutions serving them. Beyond cultural beliefs, in a pragmatic sense, the return of an individual result will affect the individual, the family, and the entire community. In Western cultural contexts, there are questions regarding the extent to which informed consent to clinical genetic testing is truly autonomous given the potential for the results to affect family members.[54] A community's philosophical understanding of genetics will underpin the ethical processes for responding to unexpected results.

B. BURDEN AND RESPONSIBILITY

In developed nations, Indigenous communities are increasingly setting their own health care priorities and managing their own health care budgets.[55] There is a potential that research could place an additional burden on the community by calling on their institutions to respond to incidental findings, particularly if their clinical relevance is unclear. Consultation with community health care providers would be essential in assessing potential additional responsibilities resulting from the return of incidental findings. Communities may require financial support to provide genetic counseling services to their members, and health care providers may need additional training to understand genetic risk factors for disease. From the outset of research, the community and researchers should determine who will bear the responsibility for financial or educa-

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53. Gillett & McKergow, *supra* note 8, at 2098.

54. Nina Hallowell, *Consent to Genetic Testing: A Family Affair?*, *in* THE LIMITS OF CONSENT: A SOCIO-ETHICAL APPROACH TO HUMAN SUBJECT RESEARCH IN MEDICINE 185, 187–88 (Oonagh Corrigan et al., eds., 2009).

55. ANNE-KATRIN ECKERMANN ET AL., BINAN GOONJ: BRIDGING CULTURES IN ABORIGINAL HEALTH 199–202 (3d ed. 2010) (discussing the increase in Aboriginal community-controlled health services).

tional support.

C. A PLACE FOR COMMUNITY CONSULTATION

There is a large amount of literature on the ethical guidelines of clinical predictive genetic testing in familial diseases, and one of the most discussed familial diseases is Huntington's Chorea.[56] Based on the right to confidentiality in Western medical ethics, the privacy of the individual trumps the right of family members to learn if they are at risk. An incidental genetic finding is akin to a predictive genetic test in that it offers a risk factor for developing a certain disease. Port et al. described how a Maori tribe modified the clinical genetic service provided to them to make the process of receiving results from genetic testing more culturally appropriate.[57] For example, provisions were made so that Maori patients could have their extended family present when receiving results.[58] Already established processes for predictive genetic testing in a community may aid researchers in the development of appropriate policies for the return of incidental findings. However, simply following clinical care procedures may contribute to therapeutic misconception. Community consultation would be required to develop policies for return of results specific to the research conducted.

D. CONFIDENTIALITY

Any community and its members may desire confidentiality in return of results, but additional protections will have to be put in place, especially within small communities. Communal informed consent implies that all community members would know the purpose of the research, the timeline, the researchers, and the potential for incidental findings.[59] In geographically-isolated communities or on reserves and reservations, everyone knows who is visiting the region. It is unclear how individuals could keep their status private if, for example, they are required to make an appointment with a visiting genetic counse-

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56. *See e.g.*, Int'l Huntington Ass'n & the World Fed'n of Neurology Res. Grp. on Huntington's Chorea, *Guidelines for the Molecular Genetics Predictive Testing Huntington's Disease*, 31 J. MED. GENETICS 555, 555 (1994).

57. R.V. Port et al., *Cultural Enhancement of a Clinical Service to Meet the Needs of Indigenous People; Genetic Service Development in Response to Issues for New Zealand Maori*, 73 CLINICAL GENETICS 132, 135 (2008).

58. *Id.*

59. *See* Burgess & Tansey, *supra* note 44 at 201.

lor. In a small community there may also be only one health provider. Even if results are returned privately, follow-up care would be conducted or facilitated by that local provider. Only through community consultation could researchers devise how to manage this process confidentially and learn what additional protection the community would need.

E. THE PUBLIC'S RIGHT TO KNOW

At a philosophical level, given that the entire community could bear the responsibility of return of individual results though priority shifts in health care provision or a general knowledge of increased risk for a disease within a family, does the public have a right to the knowledge of individual results?

Many Indigenous people live simultaneously in their cultures and the Western world.[60] Balancing a communal value of collective stewardship of genes and a Western value of confidentiality of individual results may be necessary not only in the context of writing a research agreement between a community and an academic researcher, but also within the mind of each research participant. At the heart of this is the question: where does the scientific, reductionist concept of genetics fit within a potential holistic understanding of well-being?[61] How does the individuality of one's genetic make-up—one's genetic destiny—align with the ideas of interconnectedness? In embarking on genetic research with an Indigenous community, it is necessary to explore with the community the meaning of genes within their culture.

V. SELF-DETERMINATION AND SECONDARY RESEARCH

McGuire and Beskow outline many of the implications for informed consent that flow from genetic and genomic research.[62] Given that there is limited control over future use of

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60. *E.g.*, *Frequently Asked Questions About the Arctic*, NAT'L OCEANIC & ATMOSPHERIC ADMIN., http://www.arctic.noaa.gov/faq.html (last visited Apr. 1, 2012) (stating that Indigenous people blend parts of Western civilization—such as city water and sewerage, food markets, and the internet—into their lifestyle).

61. *See generally* Elana Brief & Judy Illes, *Tangles of Neurogenetics, Neuroethics, and Culture*, 68 NEURON 174, 174 (2010) (considering "indigenous concepts that render notions of 'individual ownership' of genes problematic").

62. Amy L. McGuire & Laura M. Beskow, *Informed Consent in Genomics and Genetic Research*, 11 ANN. REV. GENOMICS & HUM. GENETICS, 361, 363

samples, an individual effectively relinquishes some autonomy in not being able to withdraw from future, unknown research.[63] Recognizing that indigenous peoples own their genetic resources, relinquishing rights around the future use of biological materials is antithetical to self-determination.[64]

Research guidelines have been established around ownership of data and materials. An example is the Canadian First Nation Principles of OCAP (Ownership, Control, Access, and Protection), first described by the National Steering Committee of the First Nations Regional Longitudinal Health Survey.[65] Schnarch described OCAP as "self-determination applied to research," where the principles are based on Indigenous rights and instruct researchers in decision-making in the context of their research.[66] OCAP serves the interests of First Nations and holds researchers accountable to the Nation's ethical framework, while institutional review boards serve academic interests based on Western ethics.[67] Evaluating research against OCAP principles therefore complements the work conducted by institutional ethics review boards by simultaneously incorporating Indigenous and Western philosophies in the assessment of research. Schnarch articulated how the four principles of OCAP can guide researchers to conduct non-exploitative research, from the perspective of indigenous peoples.[68] Ownership is the assertion, or assumption, that cultural or ancestral knowledge is owned collectively by the Nation.[69] In the context of a research project, the consent process for the use of a Nation's cultural knowledge ought to include a communal component.[70] Control refers to the rights of indigenous peoples to regain and maintain control over all aspects of their lives, or

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tbl.1 (2010).

63. *Id.*

64. *See* Kara H. Ching, *Indigenous Self-Determination in an Age of Genetic Patenting: Recognizing an Emerging Human Rights Norm*, 66 FORDHAM L. REV. 687, 716–18 (1997) (discussing "whether, and to what extent, [the group right of an indigenous people to decide] to participate in genetic research should be recognized as within the scope of self-determination").

65. Brian Schnarch, *Ownership, Control, Access, and Possession (OCAP) or Self-Determination Applied to Research: A Critical Analysis of Contemporary First Nations Research and Some Options for First Nations Communities*, 1 J. ABORIGINAL HEALTH, Jan. 2004, at 80, 80–81.

66. *Id.* at 80.

67. *Id.* at 93.

68. *Id.* at 80–81.

69. *Id.* at 81.

70. *Id.*

to self-determine.[71] Research projects have the potential to do harm to individuals, families, communities, and the Nation as a whole. To prevent harms, a Nation has the right to assert control over the research, including defining the scope of the project, determining how resources are used, as well as directing a research review process. It is critical for a First Nation to be able to review how information is shared with researchers and how the knowledge gained through research is translated, documented or portrayed. Reviewing the research ensures that sensitive knowledge, if used, is shared in a way that does not harm the people of that Nation. Access is the right of indigenous peoples to be able to access data that concerns them and their communities.[72] Management of these data—and decision-making surrounding access to data—is the Nation's collective right. Possession, while "not a condition of ownership per se, . . . is a mechanism by which ownership can be asserted and protected."[73] These guidelines or protocols can help researchers to determine if their research is exploitative or beneficial to indigenous peoples and their interests.[74] The question of whose interests a particular research project intends to serve can be made transparent through OCAP.

Indigenous self-determination in the context of research is multi-faceted. Work done in the name of research may undermine an indigenous people who are working towards self-determination in the face of historic and contemporary disruption to their cultures, lands, and economic structures. Indigenous control of research challenges the legitimacy of academic and clinical research and the foundations upon which Western research methodologies have emerged. Legitimacy of Indigenous governance systems and their resurgence is one essential component of self-determination. OCAP is one means by which this resurgence can occur.[75]

Given the political and ethical imperatives, it would be impossible to conduct secondary research on archived genetic materials from an Indigenous Nation stored in biobanks without community consent. Just as in primary research, then, a pro-

71. *Id.*
72. *Id.*
73. *Id.*
74. Kovach, *supra* note 51, at 145.
75. Schnarch, *supra* note 65, at 80–81.

cess for return of incidental findings must be created in collaboration with the community.

CONCLUSION

The return of incidental findings has implications for individuals, their communities, and their health and social institutions. It is not reasonable or ethical to espouse a pan-Indigenous solution for the 300 to 350 million Indigenous people worldwide, representing six percent of the world's population and 5000 distinct peoples in seventy-two countries. However, a pan-research solution can be adopted to ensure that researchers fulfill their responsibility to understand specific perspectives of community in how to handle unexpected findings. A pan-research solution also cautions against assuming that Western ethics provide the answer, and recommends development and implementation of a management plan for unexpected findings specific to community through a pre-research engagement process that is mutually-informed and fluid to accommodate the dynamic nature of science.

CABs should be established and composed of community members who are recognized for their ability to reflect on implications of health-related research from the perspective of the community's values. In collaboration with the CAB, academic and clinical researchers, together with their institutional ethics review boards, should create respectful procedures for return of results of incidental findings. To address the three main issues on which we have focused here—the rights of individuals, community members, and community agencies—processes must include consideration of the following key questions:

- How will results be returned? In particular, will it be a private, family or communal process? Who assembles the meeting—the researcher, a clinician, a community elder, the individual?
- Which agencies have a right to knowledge of the incidental findings (based on the possibility that if many people have the same incidental finding then community organizations may need to prepare)? How clinically relevant would the result have to be to alert community agencies of the finding?
- Who is responsible for necessary follow-up consultation and care (e.g., hiring genetic counselors)? How will the

individual's privacy be protected in a rural or remote setting?

All plans should be discussed and understood by the community and individuals during the informed consent process.

Finally, findings that are ultimately medical in nature may appropriately be classified as personal health information. We must together consider the processes needed to recognize this possibility and honor the privacy and meaningfulness of health information that emerges in research, however unexpectedly, fortuitously, or tragically.