V.3 – July 8, 2024

Cultural Awareness Guide for those working with Indigenous Genomic Data

for the Silent Genomes Research Project *Precision Diagnosis Study (Activity 2)* and *Building an Indigenous Background Variant Library (Activity 3)*



Adapted from: 'Genetic Counselling Guide, v.3, 2021', Sarah McIntosh and Karen Jacob, The Silent Genomes Project

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I. INTRODUCTION

The aim of this document is to support individuals within the Silent Genomes Project (SGP) who are working with Indigenous genomic data and aid in ongoing learning about Indigenous cultural safety and sovereignty.

The Silent Genomes Project is a Canada-wide initiative that aims to bridge the gap in profound health inequities affecting Indigenous Peoples*. For many non-Indigenous research staff, it is the first time they are involved with working and interacting with the Indigenous Peoples of Canada substantively. In essence, we are bringing together two world views as we build the foundation for Indigenous genomic health research.

*Throughout this guide, Indigenous Peoples includes First Nations (status and non-status), Inuit, and Métis Peoples.

We are going to expound on two aspects of ownership and control of Indigenous genomic data within the realm of cultural safety.

Indigenous cultural safety

Cultural safety can apply to different peoples and circumstances, but in this context where we are speaking to Indigenous Cultural Safety, it is a stand-in for respect and honor of Indigenous Peoples. It is ensuring that Indigenous peoples feel comfortable, respected, and safe to be themselves and to express their unique cultures, world views, languages, practices and opinions as it relates to their lived experiences and knowledge. **Cultural safety for Indigenous genomic data starts with Indigenous Peoples.**

The (British Columbia) First Nations Health Authority defines cultural safety as "an outcome based on respectful engagement that recognizes and strives to address structural and interpersonal power imbalances" (FNHA's Policy Statement on Cultural Safety and Humility). It is an ongoing process that considers how social and historical contexts shape health and healthcare experiences. For example, it can mean in practice:

• embedded support of Indigenous partners as self-determining decision makers and Nations (on a large scale);

or

• providing space for ceremonies or practices, quietly or as a group in a laboratory (on a small scale)

It is not a responsibility to be taken lightly or easily. Cultural safety is, first of all, defined by those who receive the service or care, not by those who provide it. For the SGP, recipients of cultural safety include, but are not limited to, Indigenous patients and their families, Indigenous participants in the Indigenous Background Variant Library (IBVL), Indigenous staff from organizations, committees, governments, or visitors, and Indigenous manager(s) and co-workers. Likewise, Indigenous staff must also walk carefully when working with individuals, communities and families from different Indigenous Nations. Willingly or not, those same staff learn to use their voice to advocate on behalf of their Indigenous relations.

Cultural awareness to work with Indigenous Data, v.3, July 8 2024

We all have a role to play and it is continual. We are asking Silent Genomes team members and those who work with us to commit to listening and learning in order to enhance our knowledge and awareness of racial biases, to respect and honor Indigenous voices and stories, to reverse the impacts of colonization on Indigenous health and well-being, and to carry out culturally safe health research practices as defined by and with Indigenous Peoples.

DNA on Loan

The defining principle of DNA on loan is that "DNA is to be on loan to the researcher for the purpose of the research for which consent was obtained" (Arbour and Cook, 2006). DNA on Loan strengthens community-based participatory research as an aspect of self-determination – to determine one's own priorities and have them addressed through research and methodologies acceptable to both community and researcher.

To carry out research in this manner, a researcher recognizes that their personal beliefs and scientific methodology may not be consistent with those of the Indigenous community or communities they are working with. Continual communication to seek understanding, as well as flexibility and consensus to plan and carry out informative research with useable results by both parties, provides opportunities for mutual learning.

Within the Silent Genomes Project, all of the biomedical samples and genomic data generated from these samples follow that "all blood and tissues [...] is considered the property of the donor or community, and is on loan". The researcher is the steward and must handle the samples and data derived from them with respect. This includes, but is not limited to, return of biological samples and data where possible and if wished for by the community or the participant. Secondary uses are unauthorized unless expressly stated. In some cases, individual consent allows for 'future research' with Indigenous community/representative approval. Representative approval is consistent with the concept of DNA on loan.

The CARE Principles for Indigenous Data Governance

Collective benefit; Authority to control; Responsibility; and Ethics

The current movement toward open data and open science does not fully take into consideration Indigenous Peoples' rights and interests. Existing principles such as <u>FAIR – Findable</u>; Accessible; <u>Interoperable</u>; Reusable; do not go far enough or may even contradict Indigenous sovereignty and self-determination.

Indigenous data sovereignty reinforces the rights of Indigenous Peoples to engage in decision-making in accordance with Indigenous values, collective interests and rights.

II. WHAT IS THE PURPOSE OF PRODUCING AND ANALYZING INDIGENOUS GENOMIC DATA FOR THE SILENT GENOMES PROJECT?

This document applies to processing genomic data as part of Activity 2, the Precision Diagnosis Study; and Activity 3, the Indigenous Background Variant Library. The Precision Diagnosis Study offers genetic counselling and whole genome sequencing to Indigenous families with respect to cultural safety, while the Indigenous Background Variant Library is a reference database of the DNA variants in a cohort of Indigenous individuals without severe genetic conditions from across Canada.

For more information on Activity 2 of the Silent Genomes Project: <u>Precision Diagnosis for Indigenous</u> <u>Families with Genetic Conditions (Precision Diagnosis Study)</u>.

For more information on Activity 3 of the Silent Genomes Project: <u>Building an Indigenous Background</u> Variant Library (IBVL) in Canada (Activity 3).

This document will indicate recommended readings for users to start the journey toward an increased understanding of the Indigenous Peoples you may work or come in contact with, as well as the respectful use of data originating from Indigenous Peoples that you may be handling. The goal is to generate increased self-awareness to ensure a climate where the experiences of Indigenous Peoples shaped by colonial governments and practices are recognized, and Indigenous Peoples are respected for their resiliency and humanity, as appropriate care and services are provided in an equitable, safe and non-discriminatory way.

Why is genomic inequity relevant to our research study?

"Indigenous people (First Nations, Métis and Inuit) have waited far too long for their legal rights to be recognized. And they have waited too long for health-system leaders to dismantle the racism that was built into our colonial health-care system — racism that continues to cause harm to this day" - Racism in Health Care: An Apology to Indigenous People and a Pledge to Be Anti-Racist, May 11, 2021

Firstly, racism is not only active structurally, in words and actions, it is evident in the absence of healthcare and tools, or barriers to their use, which results in a significant gap in genomic health care for Indigenous Peoples. An example of this absence is the current lack of Indigenous variant data in publicly available reference databases. Variant databases are primarily based on data from people of European ancestry. Because of this, finding a genetic diagnosis can take more time and be less accurate for Indigenous patients. In this case, it is a genetic background reference library built with Indigenous co-workers, staff and partners for Indigenous patients to benefit from novel scientific discoveries and technology. The current situation to acquire a diagnosis takes more time and is less accurate because variant databases are generally based on data from people of European ancestry (although some non-European countries are now generating background variant libraries from data from their own citizens). By making the Indigenous Background Variant Library a reality, we work toward closing the health outcomes gap between Indigenous Peoples and the rest of Canadian society.

Secondly, the paucity of Indigenous healthcare providers and researchers in these fields likely contributes to this genomic divide. Less than 1% of physicians in Canada are Indigenous¹, there are no known Indigenous genetic counsellors, and only a handful of Indigenous graduate students in medical genetics. There is a need to create opportunities and supports for Indigenous Peoples to become involved in genomic healthcare, such as the scholarships and supports for Indigenous students in genetics available through the Silent Genomes project, as well as provide a welcoming healthcare and learning system that values their lived experiences and knowledge. Simply put, there is nothing like a healthcare provider with a familiar face, way of communicating, and perhaps even personal experience with the patient's larger history, often unknown by the greater Canadian society.

What is appropriate use of Indigenous data in the Silent Genomes Project?

Activity 2

In order to analyze genomic data for precision diagnosis, the Activity 2 bioinformatics team has access to two types of <u>de-identified data</u>: (1) *clinical data* and (2) *genomic data*.

1. Clinical data

Bioinformaticians working on the project are able to access de-identified phenotypic data to be used for the purposes of genomic analysis within the scope of the Silent Genomes Project only. Phenotypic data is accessible via the REDCap database.

2. Genomic data

De-identified *genomic data* generated from Activity 2 for Level 1 and 2 analysis (including FASTQ, BAM, and possibly VCF files) are available for downloading from the Genome Sciences Centre (GSC) where the genome sequencing is carried out, to the BC Children's Hospital Research Institute (BCCHR).

Genome data is only to be used in conjunction with phenotypic data to assess potentially pathogenic variants relating to the phenotypic presentation of the proband. Although processes are designed to maximize the detection of pathogenic variants underlying the proband's disease while minimizing unintentional discovery of clinically significant actionable variants unrelated to the current health status of the participant, it is still possible that incidental findings may be determined. Such incidental findings will be reported as appropriate in following study protocols and in the Canadian College of Medical Geneticists' position statement regarding incidental findings (Boycott et al, 2015), on a case-by-case basis. Candidate variant lists will be shared with Activity 2 team members via the secure REDCap database. This data should not be shared in any way outside of the Activity 2 research study without the proper permissions in place. The Activity 2 clinical team is responsible for returning any actionable results and other results relevant to the diagnosis to referring healthcare providers.

Here is a non-exhaustive list of what is <u>not</u> allowed to be done using the Precision Diagnosis Study participants' genomic data:

- Releasing data outside of study team or BCCHR;
- Sharing your data access privileges (username, passwords) with anyone;
- Accessing more participant data than is required for your role;
- Performing any testing or analysis outside of the specific purpose of this project;
- Purposely searching for incidental findings in participants or their family members;
- Tracing ancestry or looking for markers of 'Indigeneity';
- Publishing data without review/permission from the Silent Genomes team and relevant stakeholders (see Activity 2 "Dissemination Policy" for more details);
- Re-identifying participant data (with personal identifiers such as name and date of birth) unless it is within your role for the delivery of clinical care.

If in doubt, the user should always refer to their team lead or their day-to-day supervisor (if different).

The protocol for accessing and using data is outlined in detail in the Standard Operating Procedures (SOPs) for the Silent Genomes Project. No matter the case, it is important that project members with access to the IBVL understand the cultural context around the data. This will ensure that work will be completed in a culturally safe manner.

For more information, refer to:

Research Protocol: Precision Diagnosis for Indigenous Families with Genetic Conditions, v.6, 12 Aug 2020. Approved by UBC-Children's & Women's Hospital REB & Island Health REB (#H18-00726).

Activity 3

In order to analyze genomic data for generating the IBVL, the Activity 3 bioinformatics team will have access to *genomic data* only.

Genomic data:

In order to produce the IBVL, team members from Activity 3 have access to genomic data from Indigenous participants without severe pediatric onset genetic conditions who consented for genetic research. Since participation in Activity 3 contributes to population reference data, rather than direct individual health information, no individual results will be returned. This is consistent with what has been consented to with stored samples of the Alliance study (which will comprise the largest proportion of the IBVL) and is consistent with plans for enrollment of First Nations participants in BC. The terms of access and appropriate use of the variants contained in the Indigenous Background Variant Library for clinical diagnostic purposes will be guided by governing bodies such as the Indigenous-led Indigenous Rare Disease Diagnosis Steering Committee and the First Nations Health Authority.

Whether a team member has access to de-identified individual data or only aggregated population data depends on their role in the project. A user's scope of access to data will be decided after discussion with their team lead and day-to-day supervisor (if different). Protocol for accessing and using data is outlined in detail in the SOPs for the Silent Genomes Project. No matter the case, it is important that project members with access to the data generated through the Silent Genomes Project read and understand the cultural context around the data. This will ensure that your work will be completed in a culturally safe manner.

Here is a non-exhaustive list of what is <u>not</u> allowed to be done using the Indigenous participants' genomic data:

- Releasing data outside of study team;
- Sharing your data access privileges (username, passwords) with anyone;
- Accessing more participant data than is required for your role;
- Performing any testing or analysis outside of the specific purpose of this project;
- Purposely searching for incidental findings in participants;
- Tracing ancestry or looking for markers of 'Indigeneity';
- Publishing data without review/permission from the Silent Genome team and relevant stakeholders.

If in doubt, the user should always refer to their team lead or their day-to-day supervisor (if different).

For more information, refer to:

Research Protocol: Building an IBVL in BC, v.2, 04 August 2020. Approved by UBC-Children's & Women's Hospital REB, University of Victoria REB, and First Nations Health Authority (#H20-00131)

III. READINGS AND RESOURCES

Here we present a compilation of readings and resources that will aid in building a better understanding of how inequity in genomic technologies and precision diagnosis came about and why cultural safety is a necessary part of working with Indigenous participants' genomic data. Readings with a checkmark are recommended as part of this training and are specific to privacy, confidentiality, and handling of Indigenous genomic data.

Even though some resources are considered 'recommended', and others 'suggested', for those who have or will have access to the genomic data produced as part of the Silent Genomes Project, cultural safety is an on-going process. We encourage users to take time throughout the duration of the project, to learn from new resources, to exchange with other team members, and continue their journey toward cultural safety.

Table 1.	Relevant	Guidelines
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Project Guidelines	Description	Details
TCPS2 Policy Statement:Canadian Institutes of Health Research, Natural Sciencesand Engineering Research Council of Canada, and SocialSciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for ResearchInvolving Humans, December 2018.TCPS 2: CORE tutorial	The core ethical policies for carrying out research involving humans. *Focus on Chapter 5 about privacy and confidentiality* *Focus on Chapter 9 on research involving Indigenous Peoples*	✓ TCPS2 online tutorial is <u>required</u>
 First Nations OCAP Principles: The First Nations Information Governance Centre. <u>Ownership, Control, Access and Possession (OCAP™): The</u> Path to First Nations Information Governance. May 2014. OCAP website: <u>https://fnigc.ca/ocap-training/</u> Video: <u>Understanding the First Nations Principles of OCAP™:</u> <u>Our Road Map to Information Governance (Short)</u> The First Nations Information Governance Centre (FNIGC) developed in partnership with Algonquin College Corporate Training "The Fundamentals of OCAP®", an online training course (\$249 (plus GST/HST). 	Set of standards for how First Nations data should be collected, protected, used and shared. Additional website and video options are suggested.	 ✓ Recommended reading pages 4- 12 of the document

Table 2. Research Ethics Resources

Research Ethics	Description	Details
Arbour L and Cook D. <u>DNA on Loan: Issues to</u> <u>Consider When Carrying out Genetic Research</u> <u>with Aboriginal Families and Communities.</u> <i>Community Genet</i> ics. 2006, 9:153–160.	Guides how DNA from Indigenous research participants should be collected, stored, and used. All the genomic data obtained as part of the Silent Genomes Project is 'on loan' to researchers and their institution.	Recommen- ded reading
Caron NR, Chongo M, Hudson M, et al. Indigenous Genomic Databases: Pragmatic Considerations and Cultural Contexts. Front Public Health. 2020; 8:111. Published 2020 Apr 24. doi:10.3389/fpubh.2020.00111	Summarizes two initiatives for building a BVL (The Silent Genomes Project in Canada and Aotearoa Variome project in New Zealand), and discusses the international guidelines and ethical considerations of both initiatives.	Recommen- ded reading
Hudson M, Carroll SR, Anderson J, Blackwater D, Cordova-Marks FM, Cummins J, David- Chavez D, Fernandez A, Garba I, Hiraldo D, Jäger MB, Jennings LL, Martinez A, Sterling R, Walker JD, Rowe RK. Indigenous Peoples' <u>Rights in Data: a contribution toward</u> <u>Indigenous Research Sovereignty.</u> Front Res Metr Anal. 2023 May 4;8:1173805. doi: 10.3389/frma.2023.1173805.	The manuscript explores Indigenous Research Sovereignty, or Indigenous self- determination in the context of research activities, focusing on on the relationship between Indigenous Data Sovereignty and efforts to describe Indigenous Peoples' Rights in data.	Recommen- ded reading
Garba I, Sterling R, Plevel R, Carson W, Cordova-Marks FM, Cummins J, Curley C, David- Chavez D, Fernandez A, Hiraldo D, Hiratsuka V, Hudson M, Jäger MB, Jennings LL, Martinez A, Yracheta J, Garrison NA, Carroll SR. <u>Indigenous</u> <u>Peoples and research: self-determination in</u> <u>research governance.</u> Front Res Metr Anal. 2023 Nov 15;8:1272318. doi: 10.3389/frma.2023.1272318.	This paper broadens the concept of Indigenous Data Sovereignty by using the CARE Principles for Indigenous Data Governance to discuss how research legislation and policy set expectations around recognizing sovereign relationships, acknowledging rights and interests in data, and enabling Indigenous Peoples' participation in research governance.	Recommen- ded reading
Hudson M, Beaton A, Milne M, Port W, Russell K, Smith B, et al. <u>Te Mata Ira: Guidelines for</u> <u>Genomic Research with Māori</u> . [Report]. Māori and Indigenous Governance Centre, University of Waikato (2016).	Framework and guidelines for genomic research with Maori in New Zealand.	Recommen- ded reading

Boycott K, Hartley T, Adam S, Bernier F, Chong K, Fernandez BA, Friedman JM, Geraghty MT, Hume S, Knoppers BM, et al.; <u>Canadian College</u> <u>of Medical Geneticists. The clinical application</u> <u>of genome-wide sequencing for monogenic</u> <u>diseases in Canada: Position Statement of the</u> <u>Canadian College of Medical Geneticists.</u> J Med Genet. 2015 Jul;52(7):431-7. doi: 10.1136/jmedgenet-2015-103144. Epub 2015 May 7. PMID: 25951830; PMCID: PMC4501167.	Guidelines to report incidental findings following the Canadian College of Medical Geneticists position statement regarding incidental findings	Recommen- ded reading
Ward C, Branch C and Fridkin A. <u>What is cultural</u> <u>safety- and why should I care about it?</u> <i>Visions</i> . 2016, 11(4):29-32.	Explains what cultural safety is, and why it is important.	Suggested reading
Billan J, Starblanket D, Anderson S, et al. <u>Ethical</u> <u>research engagement with Indigenous</u> <u>communities</u> . J Rehabil Assist Technol Eng. 2020; 7:2055668320922706. Published 2020 Jun 22. doi:10.1177/2055668320922706	Indigenous Peoples are resilient in ensuring their sustainability and have far more community engagement and direction. Developing culturally safe approaches to care for Indigenous communities leads to self-determined research. Culturally safe training modules can be applied to marginalized demographics.	Suggested reading
In Plain Sight, Addressing Racism Review Full Report, November 2020	Addressing Indigenous-specific Racism and Discrimination in B.C. Health Care	Suggested reading
Silent Genomes Project: Resources and Best Practices in Genetic/Genomics Research and Clinical Care for Indigenous Peoples	A toolkit for those working in the area of genetics/genomics in order to understand optimal research practices and ensure the safety of Indigenous people engaged in research.	Suggested reading
Hayward A, Sjoblom E, Sinclair S, Cidro J. <u>A New</u> <u>Era of Indigenous Research: Community-based</u> <u>Indigenous Research Ethics Protocols in Canada.</u> Journal of Empirical Research on Human Research Ethics. June 2021. doi:10.1177/15562646211023705	Indigenous communities across Canada have established principles to guide ethical research within their respective communities. Thorough cataloging and description of these would inform university research ethics boards, researchers, and scholars and facilitate meaningful research that respects Indigenous-defined ethical values.	Suggested reading

10.22605/RRH6411. Epub 2021 Jul 9. PMID:practice. Culturally safe, trauma- informed practice training makes cultural safety more achievable.
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Table 3. Examples of Harmful Research in Indigenous Communities

Harmful Research in Indigenous Communities	Description	Details
Tribe blasts 'exploitation' of blood samples. Dalton, R. Tribe blasts 'exploitation' of blood samples. Nature 420, 111 (2002). Genetic Researcher Uses Nuu-Chah-nulth Blood for Unapproved Studies in Genetic Anthropology - HA-SHILTH-SAH NEWSPAPER, 22 July 2013.	Media reports of the misuse of Nuu- Chah- nulth DNA for unapproved genetic studies, and the return of blood samples to the communities. This case led to development of 'DNA on Loan' principles.	✓ Recommen- ded reading
Indian (Havasupai) Tribe Wins Fight to Limit Research of Its DNA - THE NEW YORK TIMES, 21 April 2010.	Media report of the misuse of Havasupai DNA for unapproved genetic studies, and the resulting lawsuit.	
MacDonald NG, Stanwick R and Lynk, A. <u>Canada's shameful history of nutrition research</u> <u>on residential school children: the need for</u> <u>strong medical ethics in Aboriginal health</u> <u>research</u> (editorial). <i>Paediatric Child Health</i> . 2014, 19(2):64. <u>Opinion Sick Kids Website Must Reflect</u> <u>Immoral Research on Indigenous Children</u> , THE STAR 25 July 2018.	Articles and media reports on the immoral nutritional experiments Canadian government scientists carried out on Indigenous children in the 1940s- 1950s.	

Table 4. A list of courses and training to guide the user in their journey toward cultural safety

Courses and Training	Description	Price
Indigenous Relationship and Cultural Awareness Courses by Cancer Care Ontario Watch the video "CCO Importance of Indigenous Cultural Competency" to understand how these courses are relevant to all Canadians, not just healthcare providers. CCO Importance of Indigenous Cultural Competency	A series of online courses to help individuals working with First Nations, Inuit and Métis people. - Relevant to all Canadians, not just healthcare providers. - 13 courses providing knowledge about the history and culture of First Nations, Inuit and Métis People and communities. - Designed for self-paced learning - Available to anyone, free of charge	Free

Indigenous Canada by the Faculty of Native Studies, University of Alberta From an Indigenous perspective, this course explores key issues facing Indigenous Peoples today from a historical and critical perspective highlighting national and local Indigenous-settler relations.	12-lesson Massive Open Online Course (MOOC) from the Faculty of Native Studies that explores Indigenous histories and contemporary issues in Canada.	Free
San'yas Indigenous Cultural Safety Training by Provincial Health Services	On-line training program designed to enhance self-awareness, and	300 CAD
Authority in BC	strengthen the skills of those who work	(including
	both directly and indirectly with	certificate)
	Indigenous People.	

Table 5. A list of additional resources that may be of interest

Podcasts and Documentaries	Description
CBC The Current (21 June 2016). <u>Meet Dr. Nadine Caron, Canada's first female First</u> <u>Nations surgeon</u>	Interviews of physicians,
CBC The Current (10 March 2017). Dr. Michael Kirlew – <u>'Our complacency will be paid</u> for in full with children's lives,' warns Indigenous health care advocate	advocates, and journalists sharing the truths,
Voicing the Silent Genome (2 November 2020). <u>Voicing the Silent Genome</u>	challenges, and
The Code of Life Series: Bridging the Genomic Divide (27 April 2021). <u>The code of life :</u> <u>Bridging the Genomic Divide</u>	future hopes for Indigenous health and reconciliation.
Radio Canada Decouverte (24 mars 2024). Le génome silencieux des Autochtones	
Books	Description
 CBC Radio: Indigenous authors recommend books all Canadians should read: Indigenous authors recommend books all Canadians should read Gray Smith, M. Tilly: A story of hope and resilience. SONO NIS PRESS. February 1 2014. Joseph, B. 21 Things you may not know about the Indian Act: Helping Canadians make reconciliation with Indigenous peoples a reality. Page Two Books, Inc. April 2018. King, T. The inconvenient Indian: A curious account of Native people in North America. Doubleday Canada, 2012. Lux, M. Separate beds: A history of Indian hospitals in Canada, 1920s-1980s. University of Toronto Press, Scholarly Publishing Division; 1 edition. March 14 2016. Sellars, B. Price paid: The fight for First Nations survival. Talonbooks. September 5, 2016. 	A variety of fictional and non- fictional books written by Indigenous authors, and/or about the history of colonialism and Indigenous Peoples in Canada.
Sellars, B. They called me number one: secrets and survival at an Indian residential	

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school. Talonbooks. April 15, 2012.	
Sterling, S. My name is Seepeetza. Groundwood Books. November 1, 1992. Talaga,	
T. Seven fallen feathers: Racism, death and hard truths in a northern city. House of	
Anansi Press. September 30, 2017.	
Wagamese, R. Indian horse. Douglas & McIntyre. January 27, 2012.	
Film adaptation, premiered in 2017: <u>http://www.indianhorse.ca/</u>	
Weatherford, J. Indian Givers: How the Indians of the Americas transformed the	
world. Ballantine Books. November 29, 1989.	
Geddes, G. Medicine Unbundled: A Journey through the Minefields of Indigenous	
Health Care. Heritage House; 1st edition. Feb. 15 2017	