

# Access and Benefit Sharing, Canadian and Aboriginal Research Ethics Policy After the Nagoya Protocol: Digital DNA and Transformations in Biotechnology

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*Across the world, the manner in which researchers access genetic resources and associated knowledge of Indigenous and Local Communities (ILCs) is perceived to be problematic. This is due to inequitable practices that implicate asymmetrical power relations between researchers and other stakeholders with these communities. Not only are Indigenous knowledge appropriated, ILCs' conservation ethics in dealing with genetic resources are unrequited. Consequently, a responsive system for equitable access and benefit sharing (ABS) over the utilizations of genetic resources as a combination of economic, conservation and social justice strategy coalesced in the 2010 Nagoya Protocol to the Convention on Biological Diversity. The Article focuses on the ABS dynamic in the context of Aboriginal related research to determine whether extant Canadian research ethics framework requires recalibration pursuant to the emergent global ABS regime mainly symbolized in the Nagoya Protocol and the new challenges posed by current advances in biotechnology with specific regard to the digital DNA phenomenon. While both regimes do not directly pre-empt digital DNA and the malleability of data in research contexts, we conclude that they recognize the evolutionary character of research and knowledge transformations. We argue that they can be interpreted to accommodate the ABS imperatives in these and other emergent contexts. We shed light on how Canadian researchers can effectively navigate the research ethics framework in the Aboriginal contexts given regard to the global ABS regime and the transformations in biotechnology in the post-Nagoya ABS landscape.*

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*Partout à travers la planète, la façon avec laquelle les chercheurs accèdent aux ressources génétiques des Autochtones et des communautés locales (ACL) et à la connaissance qui est rattachée est perçue comme étant problématique. Ceci est dû à l'existence de pratiques inéquitables se rapportant aux relations de pouvoir asymétriques entre les chercheurs et les autres personnes intéressées avec ces communautés. Non seulement le savoir autochtone est-il détourné, mais en plus aucune éthique de conservation des ACL dans le traitement des ressources génétiques n'est partagée. C'est pour cette raison qu'un système dynamique permettant l'accès et le partage des avantages (APA) concernant les utilisations des ressources génétiques combinant une stratégie de justice économique, de justice de conservation et de justice sociale a été incorporé dans le **Protocole de Nagoya sur l'accès et le partage des avantages** adopté en 2010. Dans cet article, les auteurs se concentrent sur le potentiel de l'APA dans le contexte de recherches en lien avec la question autochtone afin de déterminer si, dans l'état où il se trouve, le cadre éthique de recherche au Canada ne doit pas faire l'objet d'une révision en vertu du régime émergent permettant un APA global principalement symbolisé par le Protocole de Nagoya et les nouveaux défis que présentent les avancées actuelles dans le domaine de la biotechnologie tout en tenant compte du phénomène de l'ADN numérique. Bien que les deux régimes ne remplacent pas directement l'ADN numérique et l'adaptabilité des renseignements dans des contextes de recherche, les auteurs concluent qu'ils reconnaissent la nature évolutive de la recherche et des transformations du savoir. Les auteurs font valoir qu'ils peuvent être interprétés de manière à permettre les impératifs de l'APA dans ces contextes et dans d'autres contextes émergents. Les auteurs examinent la manière avec laquelle les chercheurs canadiens peuvent véritablement explorer le cadre éthique de recherche dans des contextes se rapportant à la question autochtone compte tenu du régime global de l'APA et des transformations dans le domaine de la biotechnologie dans la situation globale de l'APA à la suite de l'adoption du Protocole de Nagoya.*

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##### I. INTRODUCTION

The rapid advance in biotechnology recorded since the 20th century has unravelled the critical importance of genetic resources in innovations that have real life impact on humankind in virtually all areas of life. The scramble to access genetic resources for research and development in both private and public sectors has raised new challenges for stakeholders. Legal analysts have identified and framed the sites of conflicting interests under a simplistic binary of “providers” and “users” of genetic resources. Users refer to complex categories that deploy genetic resources for various endeavours, including research and development in various industrial sectors including, agriculture, food and beverages; pharmaceuticals and health; industrial biotechnology; the botanical and cosmetic industries; the environment and their various offshoots. Providers refer to regions and communities that are recognized as natural sources or origins of valuable genetic materials arising from their rich endowment in biological diversity and, by extension, traditional knowledge.

As a practical matter, there is no clear demarcation between users and providers of genetic resources. Those concepts naturally overlap. Perhaps, that categorization makes better sense when considering the alternate epistemic orientations in the uses of genetic resources. For example, while Indigenous and Local Communities (ILCs) of both the global South and North are recognized as “providers” of genetic resources, they are also natural users of those resources,

especially through their traditional knowledge systems.<sup>1</sup> That knowledge is often distinguished from formal Western science as the springboard of modern biotechnology which deploys genetic resources as pivotal ingredients for innovation. In this context, it has been noted that, “biotechnology represents an alternative environmental ethic, often facilitating tense epistemic interaction or convergences in regard to, generally, Indigenous knowledge and its relationship with western science and technology”.<sup>2</sup>

Globally, the process through which research and development entities access genetic material is perceived to be problematic. In addition to the problematic issue of access to genetic resources, overall, the collection of research related data and the conduct of research generally by external interests in ILCs remains equally sticky. For example, “[a]s the *Report of the Royal Commission on Aboriginal Peoples* (1999) pointed out, First Nations people have historically had a problematic relationship with researchers, academics, and other data collectors”.<sup>3</sup> This is especially the case because, generally, that experience is perceived to constitute a touchstone for inequitable or asymmetrical power relations that square up multinational entities or sophisticated institution-based researchers against ILCs in Canada and the remote parts of the world.

In the last several decades, this not-so-well charted territory has given rise to policy and legislative responses aimed at providing some clarity.<sup>4</sup> It has also given rise to rules of engagement between stakeholders in the use of genetic resources in research and development endeavours, especially where ILCs or their traditional knowledge are involved.<sup>5</sup> In regards to dealing with genetic

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<sup>1</sup> Chidi Oguamanam, “Genetic Resources & Access and Benefit Sharing: Politics, Prospects and Opportunities for Canada after Nagoya” (2011) 22:2 *JELP* 87 at 90 [Oguamanam, “Genetic Resources”].

<sup>2</sup> *Ibid.*

<sup>3</sup> First Nations Information Governance Centre (FNIGC), “First Nations Principles of OCAP”, online: < <http://fnigc.ca/ocap.html> > (accessed May 22, 2017) [FNIGC].

<sup>4</sup> While Canada is a party to the CBD, the host of its secretariat and an active participant in the negotiations of the Nagoya Protocol, it has yet to demonstrate interest in ratifying the Protocol or its domestic implementation beyond pre- and post-Nagoya attempts at gauging a potential policy direction on the subject. See, for example, Environment Canada, *Access to Genetic Resources and Sharing the Benefits from their Use in Canada: Opportunities for a New Policy Direction*, online: < [http://www.biodivcanada.ca/1AB19CC4-9C19-44B6-972B-42243654600B/accessing\\_genetic\\_e.pdf](http://www.biodivcanada.ca/1AB19CC4-9C19-44B6-972B-42243654600B/accessing_genetic_e.pdf) > ; see also Canada, CISDL, *Managing Genetic Resources in the 21 Century: Domestic Policy Guidance for Canada (2010)*, online: < [http://cisdl.org/biodiversity-biosafety/public/policies/Canada\\_2010\\_Domestic\\_Policy\\_Guidance\\_on\\_ABS.pdf](http://cisdl.org/biodiversity-biosafety/public/policies/Canada_2010_Domestic_Policy_Guidance_on_ABS.pdf) > . In nutshell, these documents provide insights into objectives and principles that could potentially determine Canada’s approach to implementing the Nagoya Protocol or, outside of Nagoya, implementation of a national ABS policy for that matter.

<sup>5</sup> See, for example, Jorge Cabrera Medaglia, Frederick Perron-Welch & Olivier Rukundo, eds, *Overview of National and Regional Measures on Access to Genetic Resources and Benefit-Sharing* (Montreal: CISDL, 2012), online: < [http://cisdl.org/biodiversity-biosafety/public/CISDL\\_Overview\\_of\\_ABS\\_Measures\\_2nd\\_Ed.pdf](http://cisdl.org/biodiversity-biosafety/public/CISDL_Overview_of_ABS_Measures_2nd_Ed.pdf) > .

resources, a notable feature of the inequity is summed up in the concept of *biopiracy*. This refers to the exploitation of genetic resources in ILCs and their associated traditional knowledge by corporations and researchers with perceived disregard to the needs and sensitivities of the custodians of those resources and knowledge.<sup>6</sup> An inherent aspect of the concept of biopiracy is the idea that ILCs are not merely and exclusively the providers or producers of genetic resources per se.<sup>7</sup> They have immemorial traditional knowledge, through which they curate those resources on a sustainable basis pursuant to their ecological worldviews.<sup>8</sup> As well, through the use of traditional knowledge, ILCs deploy genetic resources to innovative and diverse creative uses. Corporations and researchers freely ride on the back of the communities to obtain intellectual property rights such as patents, in a manner that excludes the original knowledge holders from partaking in the benefit of the innovation.<sup>9</sup>

Most of the discussions at the intersections of biotechnology, access to genetic resources, ILCs and traditional knowledge are framed around the role of intellectual property as a tool of exploitation.<sup>10</sup> However, in the intellectual property rights contexts, those complex intersections have ramifications for the research ethics landscape in ways that merit attention.<sup>11</sup>

On the backdrop of emerging national and international consciousness concerning equitable access and benefit sharing (ABS) over genetic resources, in this Article, we explore one of the major and definitive international agreements, namely, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity (NP)<sup>12</sup> crafted in response to the problem. Our aim is to determine whether the new global ABS regime pursuant to the NP requires any changes in the current research ethics landscape in Canada. We are mindful of

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<sup>6</sup> See Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants and Indigenous Knowledge* (Vancouver: UBC Press, 2006) [Mgbeoji]; Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge* (Cambridge, MA: South End, 1996).

<sup>7</sup> *Ibid.*

<sup>8</sup> Chidi Oguamanam, “Between Reality and Rhetoric: The Epistemic Schism in the Recognition of Traditional Medicine in International Law” (2003) 16 *St Thomas L Rev* 59 at 75.

<sup>9</sup> Mgbeoji, *supra* note 6.

<sup>10</sup> See, for example, Mgbeoji, *supra* note 6.

<sup>11</sup> See Kelly Bannister, “Non-Legal Instruments for the Protection of Intangible Cultural Heritage: Key Roles for Ethical Code and Community Protocols” in Catherine Bell & Robert K Paterson, eds, *Protection of First Nations Cultural Heritage* (Vancouver: UBC Press, 2009) (examines the diversity of community-generated research ethics instruments in Canada relating to research involving the intangible cultural heritage of Aboriginal Peoples) [Bannister, “Non-Legal Instruments”].

<sup>12</sup> *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity*, 29 October 2010, UNEP/CBD/COP/DEC/X/1 (entered into force 12 October 2014), online: <<https://www.cbd.int/abs/text/default.shtml>> [NP].

the perceived limitations or inadequacies of that instrument.<sup>13</sup> They are not the focus of this Article and they will not distract us.

In the first part, we describe the emerging global ABS landscape. In the second, we examine the backdrop and current realities for research ethics in Canada in relation to researchers, with a focus on Aboriginal-related research that involve genetic resources and associated traditional knowledge. In the third part, we explore publicly-funded research ethics in Canada with emphasis on how they apply to Aboriginal-related research. Part four identifies gaps or deficits in the publicly-funded research in relation to new global expectations on ABS and points to how those gaps could be plugged in order to calibrate Canadian Aboriginal-research ethics in ABS-compliant direction. In a related matter, part five calls attention to current advances in biotechnology with a specific interest in the notion of digital DNA. As a major concern, we explore whether such technological advancements have widened the gaps in the global and Canadian research ethics regime involving Indigenous Peoples or, alternatively whether the extant NP-driven ABS regime adequately pre-empted those technological transformations.

We found that the Nagoya Protocol may not have directly anticipated the manner in which digital technologies, including digital DNA facilitate the virtualization and de-linking of genetic resources and associated traditional knowledge from their sources or origins in ILCs—a situation that risks escalating the biopiracy phenomenon. Notwithstanding that concern, we insist that there is reasonable basis for progressive interpretative approach to relevant ABS instruments and trends in cognate policy making space for Aboriginal knowledge stakeholders to sustain ABS claims despite the challenge posed by digital technology. We conclude that the malleability of genetic resources and associated traditional knowledge data due to the applications of digital technologies results in a scenario analogous to the prevalence of genetic resources and associated traditional knowledge in transboundary status. And recognizing that the NP has elaborate provisions on transboundary genetic resources and transboundary traditional knowledge, counterintuitively, digital technologies may not be as problematic to ABS as it seems.

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<sup>13</sup> See Jorge Cabrera Medaglia, Frederic Perron-Welch & Freedom-Kai Phillips, “Overview of National and Regional Measures on Access and Benefit Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol” (2014) *Centre for International Sustainable Development Law*, online: < [http://www.absfocalpoint.nl/upload\\_mm/5/f/4/008c9cc8-19f3-4926-b380-5f13fd1eb705\\_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf](http://www.absfocalpoint.nl/upload_mm/5/f/4/008c9cc8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf) > . For further critical perspective on the Nagoya Protocol, see Sebastian Oberthür & G Kristin Rosendal, eds, *Global Governance of Genetic Resources: Access and Benefit Sharing After the Nagoya Protocol* (London: Routledge, 2014); Carmen Richerzhagen, “The Nagoya Protocol: Fragmentation or Consolidation?” (2014) 3:1 *Resources* 135; Konstantia Koutouki & Katharina Rogalla von Bieberstein, “The Nagoya Protocol: Sustainable Access and Benefits-Sharing for Indigenous and Local Communities” (2012) 13:3 *Vermont J of Envtl L* 513.

Furthermore, arguably, because it is difficult to obtain prior informed consent over digital genetic resources or digital DNA and associated traditional knowledge, they are potentially amenable to a pooled or centralized ABS system akin to the FAO international treaty's ABS framework. The latter is a pioneer ABS regime which the NP could look up to for synergy. In sum, we have mapped how Canadian researchers can effectively navigate the research ethics framework in light of the new international ABS regime and the evolution in biotechnology, especially as it relates to researchers and other stakeholders dealing with digital DNA generally and those working in various Aboriginal contexts who are now required to operate within the nuances of the post-Nagoya ABS research ethics landscape.

## II. PART I: NAGOYA PROTOCOL AND EMERGING ABS LANDSCAPE

### (a) The Convention on Biological Diversity

The Convention on Biological Diversity (CBD)<sup>14</sup> remains one of the key instruments that resulted from the 1992 Rio Conference on Environment and Development.<sup>15</sup> The agreed text of the instrument was adopted in Nairobi in May of the same year and opened for signature in Rio the following month. The CBD, which came into force on December 29, 1993,<sup>16</sup> has three clearly articulated objectives in Article 1: a) the conservation of biological diversity; b) the sustainable use of its components; and c) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources, taking into account all rights over those resources. The third objective of the Convention focuses on ABS. The Secretariat of the Convention on Biological Diversity (SCBD) was committed at the outset to these three objectives. Its tenacity is evident by the fact that, today the Convention is perhaps one of the most influential contemporary environmental instruments.

In regard to the third objective, the SCBD established the Ad Hoc Working Group on ABS that steered its work on the subject.<sup>17</sup> A combination of the

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<sup>14</sup> *United Nations Convention on Biological Diversity*, 5 June 1992, 1760 UNTS 79 (entered into force 29 December 1993), online: <<http://www.cbd.int/convention/convention.shtml>> [CBD].

<sup>15</sup> Canada, Science and Technology Division, *The Rio Earth Summit: Summary of the United Nations Conference on Environment and Development*, by Stephanie Meakin, November 1992, online: <<http://publications.gc.ca/Collection-R/LoPBdP/BP/bp317-e.htm>> .

<sup>16</sup> As at June 4, 1993 the Convention had garnered 198 signatories. Ninety days after it recorded its 30th ratification, the Convention came into force. As at the time of the present article, there are 168 signatories and 157 ratifications of the Convention.

<sup>17</sup> See “Working Group on Access & Benefit Sharing” *Convention on Biological Diversity*, online: <<https://www.cbd.int/abs/wgabs/>> (accessed May 7, 2017).

SCBD's other initiatives in interrelated areas, specifically through the work of the Ad Hoc Working Group on Article 8(j)<sup>18</sup> of the Convention, resulted in the 2000 Bonn Guidelines on Access to Genetic Resources and the Sharing of the Benefits Arising out of their Utilization.<sup>19</sup> The Bonn Guidelines articulate the key elements or principles to guide those who seek to source genetic resources from ILCs, including researchers, corporations and diverse entities. Before further discussing the Bonn Guidelines and its metamorphoses, we need to mention the substance of Article 8(j) of the CBD, which is addressed to contracting parties but is directly relevant to researchers who seek genetic resources from ILCs. In the Canadian context, this is a direct reference to researchers who source genetic resources from Aboriginal Peoples or communities in Canada. Article 8(j) of the CBD provides:

Each Contracting Party shall as far as possible and as appropriate: (j) Subject to its *national legislation*, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the *approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices*;<sup>20</sup>

Among other considerations, the significance of Article 8(j) of the CBD lies in the link it makes across the tripartite objectives of the instrument. Perhaps even more significant is its identification of the pivotal role of traditional knowledge, innovations and practices of ILCs in the promotion of those objectives. Textually, the CBD acknowledges that traditional knowledge of ILCs is relevant to the conservation of biological diversity (first objective) and its sustainable use (second objective). CBD also warrants the need for laws, regulations and other administrative measures (“national legislation”) with the approval and involvement of ILCs that support equitable sharing of benefits (third objective) arising from the use of traditional knowledge. Although the focus of the CBD is on conserving biodiversity, the CBD has assisted in mapping the framework of appropriate terms of engagement among researchers and corporations. It covers the contexts for dealing with a wide range of biological or genetic resources, or materials,<sup>21</sup> especially where those dealings directly or indirectly engage ILCs as well as their associated traditional knowledge, practices and innovations.

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<sup>18</sup> See “Working Group on Article 8(j)” *Convention on Biological Diversity*, online: <<https://www.cbd.int/convention/wg8j.shtml>> (accessed May 7, 2017).

<sup>19</sup> Text of *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization*, 2002, online: <<http://www.cbd.int/decision/cop/?id=7198>> [Bonn Guidelines].

<sup>20</sup> Emphasis added.

<sup>21</sup> All of these expressions are defined in Article 2 of the CBD.



**(a) The Bonn Guidelines**

In addition to Article 8(j), Article 15 of the CBD makes provisions on the subject of ABS over genetic resources. It outlines ways to implement the third objective of the CBD. A combination of Articles 15 and 8(j) pursuant to the works of the two Ad Hoc Working Groups on ABS and Article 8(j) resulted in the Bonn Guidelines. In a nutshell, the latter:

[I]dentify steps in the access and benefit-sharing process with an emphasis on the obligation for users to seek prior informed consent of providers. They also identify the basic requirements for mutually agreed terms and define the main roles and responsibilities of users and providers and stress the importance of involvement of all stakeholders. They also cover elements such as incentives, accountability, means for verification and dispute settlement. Finally, they enumerate suggested elements for inclusion in material transfer agreements and provide indicative list of both monetary and non-monetary benefits.<sup>22</sup>

Unanimously, a total of 180 Parties to the CBD formally adopted the Bonn Guidelines at The Hague 6th Conference of Parties (COP) in 2002. The Guidelines are premised on 8 key principles: voluntarism, ease of use, practicability, acceptability, complementarity, evolutionary, flexibility and transparency.<sup>23</sup> The popularity of the instruments amongst State Parties to the CBD signalled a shared resolve internationally to take ABS seriously. Before and after the Bonn Guidelines, there has been proliferation of regional and national regimes on ABS which focused, for the most part, on corporate bio-prospectors and less directly on researchers.<sup>24</sup> The conduct of researchers seem confined and consigned to national or institutional ethics regimes for the conduct of research.<sup>25</sup> The traction and impetus provided by the Guidelines was evident in the call later at the 2002 Johannesburg World Summit on Sustainable Development (WSSD) for the negotiation of a binding instrument on ABS within the framework of the CBD.<sup>26</sup> That negotiation effectively commenced in 2004. After six years, it resulted in the October 2010 NP adopted at the 10th COP of the CBD in Nagoya, Japan.<sup>27</sup> The NP became the second Protocol to the CBD; the first being the Cartagena Protocol on Biosafety, which was adopted in 2000 and came into force in 2003.<sup>28</sup>

<sup>22</sup> See “Bonn Guidelines”, *supra* note 19 at 5.

<sup>23</sup> *Ibid*, art 7(a)-(h).

<sup>24</sup> See *Access and Benefit-Sharing Clearing-House* on ABS measures, online: <<https://absch.cbd.int/search?documentSchema=MSR>> (accessed May 7, 2017).

<sup>25</sup> Bannister, “Non-Legal Instruments”, *supra* note 11.

<sup>26</sup> See W Bradnee Chambers, “WSSD and International Regime on Access and Benefit Sharing: Is a Protocol the Appropriate Legal Instrument?” (2003) 12 *RECIEL* 310; Oguamanam, “Genetic Resources”, *supra* note 1.

<sup>27</sup> NP, *Supra* note 12.

<sup>28</sup> *Cartagena Protocol on Biosafety*, 15 May 2000, 2226 UNTS 208 (entered into force 11 September 2003), online: <<https://bch.cbd.int/protocol/text/>> .

In the meantime, in various regimes and fora, cardinal principles of ABS continue to be debated and integrated into legal and policy documents; this has ramification not only for corporate bio-prospectors but also for researchers involved in the utilization of genetic resources and associated traditional knowledge from ILCs. Developments in those various fora would not detain us here, as they do not constitute the substantive focus of this article. However, they merit outlining in order to demonstrate the scope of interests and the stakeholders engaged in ABS.

### (c) ABS and Cognate Matters in Other Fora and Regimes

The first is through the United Nations Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty).<sup>29</sup> The treaty was signed in 2001 and it came into force in 2004. Like the CBD, negotiations for the treaty commenced decades earlier. In essence, the International Treaty replicates the objectives and principles of the CBD rechanneling them to apply to users and producers in the narrower arena of plant genetic resources for food and agriculture (PGRFA). As such, its objectives include conservation and sustainable use of PGRFA and equitable benefit sharing arising from their use.<sup>30</sup> Specifically, the treaty recognizes the contribution of ILC farmers through their traditional knowledge, innovation and practices toward the conservation of PGRFA.<sup>31</sup> In addition to the protection of traditional knowledge relevant to PGRFA, the International Treaty provides for the rights of farmers as stakeholders to fully participate in decision making relevant to the conservation and sustainable use of PGRFA.<sup>32</sup>

The second major fora or regimes in which the ABS imperative is engaged include the plurilateral and cross-cutting sites within the international intellectual property system. To varying degrees, under virtually all regimes of intellectual property rights, the ABS imperative continues to be a crucial aspect of intellectual property law reforms aimed at strengthening the protection of traditional knowledge of ILCs.<sup>33</sup> For example, central to those considerations is the idea of disclosing the origin or source of genetic resources and, where applicable, associated traditional knowledge implicated in the potential and or actual intellectual property rights claimed by the user.<sup>34</sup> Under the patent system,

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<sup>29</sup> *International Treaty on Plant Genetic Resources for Food and Agriculture*, 3 November 2001, 2400 UNTS 303 (entered into force 29 June 2004), online: <<http://www.fao.org/plant-treaty/overview/texts-treaty/en/>> [International Treaty].

<sup>30</sup> *Ibid.*, art. 1.

<sup>31</sup> *Ibid.*, art. 9.

<sup>32</sup> *Ibid.*, arts. 9.2(b) and (c).

<sup>33</sup> See *infra* notes 34-39.

<sup>34</sup> Dominic Keating, "Access to Genetic Resources and Equitable Sharing Through a New Disclosure Requirement in the Patent System: An Issue in Search of a Forum" (2005) 87 *J of the Patent & Trademark Office Society* 525.

disclosing source or origin of genetic resources used in an invention that is the subject of a patent application and the issue of prior informed consent (PIC) of providers of such materials remain contentious. These matters are part of ongoing reforms pursuant to the Patent Co-operation Treaty, Patent Law Treaty and the Substantive Patent Law Treaty, which are all part of the WIPO Patent Agenda.<sup>35</sup>

Similarly, the same issue arises in the context of the work of two WIPO Committees. These include the WIPO Committee on the Law of Trademarks, Industrial Designs and Geographical Indications (SCT) pursuant to the Design Law Treaty (DLT),<sup>36</sup> and the WIPO's Intergovernmental Committee on Intellectual Property and Traditional Knowledge, Genetic Resources and Folklore (IGC).<sup>37</sup> The latter is charged with the task of negotiating text-based instruments designed to ensure effective protection of traditional knowledge. So far, the IGC has compartmentalized its work into three draft texts. Each of them deals with genetic resources,<sup>38</sup> traditional knowledge,<sup>39</sup> and traditional cultural expressions.<sup>40</sup> The issues of modalities for the disclosure of source or origin and for securing the PIC of ILCs, and ensuring their involvement in the context of

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<sup>35</sup> See WIPO, *Agenda for the Development of the International Patent System: Studies on the Impact of the System on Developing Countries*, WIPO, 46th Year, 39th Mtg, WIPO Doc A/39/13 (15 August 2003), online: <[http://www.wipo.int/edocs/mdocs/govbody/en/a\\_39/a\\_39\\_13.pdf](http://www.wipo.int/edocs/mdocs/govbody/en/a_39/a_39_13.pdf)> (accessed May 7, 2017); WIPO, *WIPO Patent Agenda: Options for Development of the International Patent System*, WIPO, 45th Year, 37th Mtg, WIPO Doc A/37/6 (19 August 2002), online: <[http://www.wipo.int/edocs/mdocs/govbody/en/a\\_37/a\\_37\\_6.pdf](http://www.wipo.int/edocs/mdocs/govbody/en/a_37/a_37_6.pdf)> (accessed May 7, 2017); Carlos M Correa, "An Agenda for Patent Reform and Harmonization for Developing Countries" (Paper delivered at the International Center for Trade and Sustainable Development (ICTSD), Bellagio, Italy, 24-28 September 2005), online: <[http://www.wipo.int/meetings/en/2006/scp\\_of\\_ge\\_06/presentations/scp\\_of\\_ge\\_06\\_correa.pdf](http://www.wipo.int/meetings/en/2006/scp_of_ge_06/presentations/scp_of_ge_06_correa.pdf)>. In June 2017, the World Intellectual Property Organization released a detailed study on patent disclosure requirements for genetic resources and traditional knowledge in support of ongoing negotiation pursuant to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore [or Traditional Cultural Expressions] (IGC). See WIPO, *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge (Geneva: WIPO, 2017)* [WIPO, "Patent Disclosure Requirements"].

<sup>36</sup> Catherine Saez, "Standstill on Industrial Design Treaty, Country Names, GIs in WIPO Committee", *Intellectual Property Watch* (20 March 2015), online: <<http://www.ip-watch.org/2015/03/20/standstill-on-industrial-design-treaty-country-names-gis-in-wipo-committee/>>.

<sup>37</sup> For history and more details about the IGC initiative, see <<http://www.wipo.int/tk/en/igc/>>.

<sup>38</sup> See "Genetic Resources", *World Intellectual Property Organization*, online: <<http://www.wipo.int/tk/en/genetic/>>.

<sup>39</sup> See "Traditional Knowledge", *World Intellectual Property Organization*, online: <<http://www.wipo.int/tk/en/tk/>>.

<sup>40</sup> See "Traditional Cultural Expressions", *World Intellectual Property Organization*, online: <<http://www.wipo.int/tk/en/folklore/>>.

dealings in these subject matters that involve the use of their genetic resources and, in some cases, their traditional knowledge remain contentious in the negotiations of these instruments.<sup>41</sup>

Finally, to a large extent, these multiple regime constellations that adumbrate the issue of ABS are in sync with the more political instrument, namely the 2007 United Nations Declaration on the Rights of Indigenous Peoples (UNDRIPs).<sup>42</sup> It is arguable that those instruments that are later in time than the UNDRIPs could have found inspiration in the latter's detailed provisions. A core aspect of that instrument which provides impetus for the coalescing of consciousness around ABS, especially among Indigenous Peoples, derives from Article 31, which declares:

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of flora and fauna, oral traditions, literatures, designs, sports and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge and traditional cultural expressions.

#### **(d) Researchers' Foggy Relationship with ABS**

Strictly, none of these instruments create any *direct* obligation on researchers whose work require dealings with genetic resources or other forms of vital information relevant to the use of traditional knowledge of ILCs. There are a number of reasons why. First, some of these instruments are non-binding and are designed to encourage best practices on voluntary or soft law basis. Second, even as binding treaties or declaratory instruments, they are addressed to, and create responsibilities that rest on sovereign nations as opposed to individuals or identified juristic entities.

Third, the extent to which a sovereign state may be committed to these instruments depends on the status of such a state in relation to the specific instrument and the obligation must derive from national law or regulation. For example, Canada is a party to the International Treaty as well as a party to the CBD and the host of its secretariat in Montreal. Canada adopted the Bonn Guidelines, but it has yet to accede to the NP. The country is an active participant in the ongoing negotiations pursuant to the WIPO Patent Agenda and the SCT negotiations on Design Law Treaty as well as in the IGC tripartite

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<sup>41</sup> See Daniel F Robinson, Ahmed Abdel Latif & Pedro Roffe, eds, *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (London: Earthscan, 2017).

<sup>42</sup> UNGA, *United Nations Declaration on the Rights of Indigenous Peoples*, UNGAOR, 61st Sess, Supp No 53, UN Doc A/61/295 (2007), online: <[http://www.un.org/esa/socdev/unpfii/documents/DRIPS\\_en.pdf](http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf)> [UNDRIPs].

negotiations on genetic resources, traditional knowledge and traditional cultural expression texts. But even though Canada has yet to ratify the NP, as a party to the parent treaty, the CBD, Canada should neither act nor fail to act in any manner inconsistent with the CBD, and by extension, any protocols made under it. As well, following its earlier objection to the UNDRIPs, Canada is now a later-day endorser of the instrument. As indicated below, Canada has placed itself in a position that requires it to support the objectives and principles of that declaration in good faith. Perhaps, more importantly, as *prima facie* beneficiaries of these instruments, there is a natural and logical expectation that ILCs at their different national and local levels should endeavour to take their own initiatives to ensure that these instruments are implemented. And, in so doing, pursuant to the constellations of principles around ABS in particular and other cognate ethical expectations arising from the conducts of research,<sup>43</sup> they could hold the states and various levels of governments and researchers to account.

Fourth, the impetus for equitable ABS system as reflected in these instruments is linked to rampant acts of biopiracy, which often implicate corporations engaged in bioprospecting and unrequited appropriation of genetic resources and associated traditional knowledge.<sup>44</sup> Fifth, individual researchers are often employees or agents of corporations that take ultimate responsibilities for the backlashes associated with biopiracy. Last, and perhaps most important, public sector researchers are often involved in primary and non-profit research activities which, on the surface, are perceived as less controversial and non-exploitative.<sup>45</sup> That is often juxtaposed with corporate-driven applied or commercial R&D that are perceived to abuse the intellectual property system through one-sided exploitation of genetic resources and vital information associated with traditional knowledge of ILCs. However, following the United States Bayh-Dole Act of 1980<sup>46</sup> on commercialization of public funded research and its impact globally, public sector researchers in Canada and elsewhere are increasingly entangled in a web of public-private partnerships. Such partnerships are committed to the commercialization of public research. They do not exclude research dealing with Aboriginal Peoples in an ABS dynamic. So, the assumption that research conducted by universities and other publicly funded entities are neither profit-oriented nor exploitative is no more persuasive as it is tenuous.

Despite the reservation over the direct applicability of key ABS instruments to researchers, it bears reiterating that Canada is a principal party to the CBD

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<sup>43</sup> Bannister, “Non-Legal Instruments”, *supra* note 11; see also Kelly Bannister, Maui Solomon & Conrad G Brunk, “Appropriation of Traditional Knowledge: Ethics in the Context of Ethnobiology” in James O Young & Conrad G Brunk, eds, *The Ethics of Cultural Appropriation* (UK: Wiley-Blackwell, 2009) at 140 [Bannister, Solomon & Brunk]; Oguamanam, “Genetic Resources”, *supra* note 1.

<sup>44</sup> See Mgbeoji, *supra* note 6; see Daniel F Robinson, *Confronting Biopiracy: Challenges, Cases and International Debates*, (UK: Earthscan, 2010).

<sup>45</sup> Bannister, “Non-Legal Instruments”, *supra* note 11.

<sup>46</sup> Also known as *Patent and Trademark Law Amendment Act*, 35 USC §§ 200-212 (1980).

and the International Treaty. Also, as indicated, Canada adopted the Bonn Guidelines (even though it is voluntary) and has remained an active member of the international community in the negotiation of cognate instruments. Even worthy of mention is that after nearly a decade of foot-dragging, Canada has now fully endorsed the UNDRIPs.<sup>47</sup> The current Justin Trudeau-led Liberal Government has launched an elaborate program to advance reconciliation between Canada and its Aboriginal Peoples igniting interests for an expansive and Aboriginal sensitive public policy space.<sup>48</sup> All of these indicate the need for positive domestic legislative, regulatory and research ethics system supportive of the principles espoused in key international instruments. These principles collectively strike a chord with Canada's reconciliation initiatives with regards to prior informed consent, transparency, respect and distributive justice in dealing with genetic resources and Aboriginal knowledge in ways that reflect Aboriginal Peoples' identify and self-determination.<sup>49</sup>

**(e) Drawing Researchers into ABS: The Nagoya Protocol**

Specifically, the overarching aspects of key instruments on ABS as emblematically articulated in the Bonn Guidelines and consolidated in the NP is the principle of PIC. PIC allows involving ILCs and implementing mutually agreed terms between them and those who seek to use their genetic resources or other forms of information and associated traditional knowledge.<sup>50</sup> Far more than the Bonn Guidelines, the NP provides for an elaborate way to integrate ILCs' interests and their involvement in research over the utilization of genetic resources and associated traditional knowledge to which we shall return later.<sup>51</sup> Already, the historic and asymmetric colonial power relations between Aboriginal Peoples of Canada and the dominant society stink of Aboriginal Peoples' vulnerabilities in a manner that compels the highest standards of ethical

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<sup>47</sup> See Canada, Indigenous and Northern Affairs Canada, *Canada's Statement of Support on the United Nations Declaration on the Rights of Indigenous Peoples*, (Ottawa: Indigenous and Northern Affairs Canada, 12 November 2010), online: <<http://www.aadnc-aandc.gc.ca/eng/1309374239861/1309374546142>>; see John Ivison, "First Nations Hear Hard Truth that UN Indigenous Rights Declaration is 'Unworkable' as Law", *National Post* (14 July 2016), online: <<http://news.nationalpost.com/full-comment/john-ivison-first-nations-hear-hard-truth-that-un-rights-declaration-unworkable-as-law>>.

<sup>48</sup> Canada, Justin Trudeau, Prime Minister of Canada, *Statement by the Prime Minister of Canada on advancing reconciliation with Indigenous Peoples*, (Ottawa: Justin Trudeau, Prime Minister of Canada, 15 December 2016), online: <<http://pm.gc.ca/eng/news/2016/12/15/statement-prime-minister-canada-advancing-reconciliation-indigenous-peoples>>.

<sup>49</sup> See generally, Catherine Bell & Val Napoleon, eds, *First Nations and the Law: Respect, Reconciliation and Reform* (Vancouver: UBC Press, 2010) [Bell & Napoleon].

<sup>50</sup> See provisions 19, 24-27 and 41-44 of the Bonn Guidelines. Similar provisions are contained in Articles 6 and 7 of the Nagoya Protocol.

<sup>51</sup> See Art 12 of the Nagoya Protocol.

prudence in the conduct of Aboriginal research. These standards are especially necessary for research that involve the use of resources in Aboriginal lands and research that involve epistemic sensitivities. To the degree that research ethics traverse and encompass the faint borderline between law and morality, the value of these international instruments does not necessarily lie in the degree to which they are legally binding on Canada. Rather, as aspect of evolving best practices, they point to important considerations, which prevailing Canadian research ethics cannot ignore. Of specific interest is the NP, which aside from building on the principles of the Bonn Guidelines, provides insights on how best ILCs could be ethically engaged in post-Nagoya research landscape.

The NP is fairly limited in scope to the extent that it deals with ABS over genetic resources and associated traditional knowledge. As a matter of current reality, in addition to access to genetic resources and Aboriginal knowledge issues, research-related relationships with Aboriginal Peoples happen in several other broader contexts. Such experience remains an ongoing matter for regulatory engagement across various levels of community, institutional and government interests and collaborations. Even though they are not the subject of this present Article,<sup>52</sup> a couple of such experiences, which designate integral aspects of research ethics landscape in Canada, require mentioning.

### **III. PART II: INDIGENOUS PEOPLES AND CANADA'S RESEARCH ETHICS LANDSCAPE**

One notable initiative dates back to 1997 pursuant to the First Nations Regional Health Survey (RHS), which was initiated to generate reliable health and well-being data for First Nations and Inuit. The data was necessary to produce relevant but unavailable statistics to fill gaps and enhance medical services delivery that target First Nations. The RHS has continued to be conducted on a fairly regular basis under the control and auspices of the First Nations Information Governance Committee. The latter has since metamorphosed into the First Nations Information Governance Centre (FNIGC) as a federally incorporated entity with regional First Nations communities and organizations as its members. As its principal mandate, the FNIGC plays a custodial or stewardship role over RHS data ensuring that First Nations own and control their health information. This includes ensuring that First Nations use the benefits derived from the data and their ability to develop ethically sensitive research partnerships based on the information. Under this framework, the FNIGC has since developed RHS code of ethics that outlines the guiding principles and protocols for the use of RHS data within its custody as the basis of the First Nations Research Policy Statement. In a nutshell, the statement affirms the right to self-determination of First Nations and their jurisdiction over

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<sup>52</sup> For insightful discourse of research ethics and protocols involving Aboriginal Peoples in relation to protection of traditional cultural expression and traditional knowledge more broadly, see Bannister, "Non-Legal Instruments", *supra* note 11; see also Bannister, Solomon & Brunk, *supra* note 43.

research conducted in their communities. It also affirms the right of First Nations to benefit from the results of such research through, for example, learning about and taking control of their own health and well-being in addition to receiving funding and participating in the conduct of First Nations research.

**(a) The OCAP Principles**

Perhaps more importantly, the FNIGC has since 1998 developed the famous and trademarked “OCAP Principles”. These are designed as the principal standard governing protocols for the collection of First Nations data and their protection, in addition to how they could be ethically shared, disseminated or applied. OCAP is an acronym for the right of First Nations to the Ownership, Control, Access and Possession of research data arising from any research that targets them under this framework. While the FNIGC is based on RHS and applies substantially to health research, as indicated earlier, FNIGC mandates include furtherance of research-related partnerships. As part of its other limitation, the FNIGC-RHS model focuses on First Nations and Inuit and does not apply to non-Inuit and non-First Nations Aboriginal categories. Despite these limitations, the initiative reflects an informed response to perennial complaints by Canada’s Indigenous Peoples that they have been too often subjects of Eurocentric research conducted by non-Indigenous peoples who fail to apply the benefits of the research to the communities. The *1999 Royal Commission on Aboriginal Peoples strongly captures* this sentiment. That observation serves as the catalyst for series of inward-looking initiatives by Indigenous Peoples to tackle head-on the dubious and troubled relationship between them and researchers, academics and data collectors. Therefore, beyond health information and beyond the First Nations and Inuit initiative, even before NP, Indigenous Peoples have had to negotiate, develop and create variegated procedures that address the asymmetrical and inequitable relations between them and several researchers and prospectors.<sup>53</sup> At the moment, the sentiment is toward a more appropriate context of partnership and the imperative for recognition of Indigenous methodology in the conduct of research.<sup>54</sup>

**(b) Pre-eminence of “Data” in ABS and Indigenous Research Dynamic**

Multidisciplinary researchers ranging from cartographers, ethnographers, anthropologists, economists, social scientists, critical data studies experts to lawyers doing traditional knowledge-related research by and with Indigenous communities “have witnessed the emergence of numerous issues regarding the

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<sup>53</sup> Thomas Burelli, “The decisive (but underestimated) contributions of researchers and indigenous people to frame the circulation of their traditional knowledge” (Paper delivered at the ABS Canada Symposium and Focus Group on Access and Benefit Sharing, Saskatoon, 12 May 2017) [unpublished] [Burelli].

<sup>54</sup> See, for example, Hadley Friedland & Val Napoleon, “Gathering the Threads: Developing a Methodology for Researching and Rebuilding Indigenous Legal Traditions” (2015) 1:1 Lakehead LJ 16 [Friedland & Napoleon]; see also Bell & Napoleon, *supra* note 49.



collection, dissemination and management of data based on Traditional Knowledge”.<sup>55</sup> Not only do such issues implicate the problematic relationship between intellectual property and traditional knowledge, they also touch on the subject of access and equitable sharing of benefits arising from such research. Notably, a network of researchers from Geomatics and Cartographic Research Centre (GCRC) at Carleton University have proposed an open licensing scheme for traditional knowledge.<sup>56</sup> These researchers work with northern Canadian and other Indigenous communities to develop online interactive atlases. GCRC researchers deploy geographic processing and management skills as tools of analysis for a range of socio-economic issues of interests with a focus on specific local and international contexts. According to the researchers, given the communal and other unique features of traditional knowledge not recognized under the conventional intellectual property framework, the proposed licensing scheme “aims to assist traditional knowledge holders communicate their expectations for appropriate use of their knowledge to all end users”—a development that potentially contributes to the letter and spirit of ABS and to other non-economic aspects of traditional knowledge. However, given the heterogeneity of Aboriginal Peoples and complex nuances of their cultural ecosystems, as Kelly Bannister has rightly noted, “[t]here is no easy answers or one-size-fits-all solutions. Each Aboriginal group will have to invest in creating its own solution”.<sup>57</sup> This is true regarding the suitability or applicability of the licensing or other schemes.

The critical data aspect of the GCRC seeks a moderation of the open data movement, such as the Open North<sup>58</sup> initiative. GCRC promotes critical data framing which captures the roles, biases and limitations of several factors in data interpretation. These considerations may not necessarily be the priority of the open data philosophy. Open North is part of global big data movement that deploys open data and civic technology tools at local and national scales in furtherance of “better and more open democracies”.<sup>59</sup> According to Tracey Lauriault of GCRC, “Open North is working with First Nations Leaders to define the relationship between data sovereignty and open data”.<sup>60</sup> In a conceptual orientation in which data sovereignty depicts the right to control

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<sup>55</sup> Carleton University, Geomatics and Cartographic Research Centre & Canadian Internet Policy and Public Interest Clinic (CIPPIC), *A Proposal: An Open Licensing Scheme for Traditional Knowledge* (2016), online: <[https://cippic.ca/sites/default/files/file/CIPPIC\\_GCRC-TK\\_License\\_Proposal-July\\_2016.pdf](https://cippic.ca/sites/default/files/file/CIPPIC_GCRC-TK_License_Proposal-July_2016.pdf)>.

<sup>56</sup> *Ibid.*

<sup>57</sup> Bannister, “Non-Legal Instruments”, *supra* note 11 at 303.

<sup>58</sup> See “For Better More Open Democracy”, *Open North*, online: <<http://www.open-north.ca/#what-we-do>> (accessed 5 June, 2017).

<sup>59</sup> *Ibid.*

<sup>60</sup> Tracey P. Lauriault, “Critical Data Studies, Smart Cities and Precision Farming” (CIPPIC Summer Seminar Series, delivered at the University of Ottawa, 16 May 2017) [unpublished; on file with lead author].

access and determine how an individual or communally held data is used, the OCAP principles explored earlier in this section is an aspect of data sovereignty. An ethical framing of data from Indigenous research contexts focuses on the relationship or relevance of such data as framed or deployed in a research context to justice, equity, fairness, honesty, and rights as they relate to Indigenous Peoples. In this regard, Lauriault notes: “open data community needs to critically reflect on its worldview and how it differs from that of Indigenous Peoples”.<sup>61</sup> As Aboriginal Peoples continue to partner in multi-disciplinary data-driven research that are increasingly publicly accessible through the internet,<sup>62</sup> the interpretation and the scope of use of such information, especially by the general public, and the control and ownership of those data and their derivatives pose new research ethics challenges, including those relating to ABS.

In addition to the foregoing, scholars continue to explore the on-the-ground reality of how Indigenous Peoples in Canada have engaged external researchers working in their communities. According to Thomas Burelli, well before the NP and its emerging ethical landscape on ABS, researchers and Indigenous communities have been using many unique and often times local-specific tools, such as contracts, protocols, trust-based relationships to negotiate terms of engagement including those relevant to ABS over genetic resources and associated traditional knowledge. Kelly Bannister’s 2009 study of community-led protocols developed in partnership with researchers and institutions in the area of intangible cultural heritage found that “[r]ecent funding programs with a specific focus on Aboriginal and community-based participatory research have stimulated and enabled the development of a number of new community-level instruments and strategies that are of higher degree of sophistication than has been seen in the past”.<sup>63</sup>

Thomas Burelli suggests that NP does not necessarily require the re-invention of the wheel. Rather, it contributes to raise consciousness over lingering inequity between ILCs and research or bioprospecting entities within the narrow parameters of ABS.<sup>64</sup> NP recognizes the legal relevance of community protocols in regard to ABS over genetic resources. Given that such protocols arise from Indigenous legal traditions, NP vindicates the call for the integration of Aboriginal legal traditions in negotiating relationships with Aboriginal Peoples.<sup>65</sup> Beyond these practical insights that highlight the current

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<sup>61</sup> *Ibid.*

<sup>62</sup> See, for example, Brian Thom-led ethnographical project: Ethnographic Mapping Lab, University of Victoria, “Stz’uminus storied places”, online: < <https://www.uvic.ca/socialsciences/ethnographicmapping/projects/stzuminus/index.php> > (accessed June 5, 2017).

<sup>63</sup> Bannister, “Non-Legal Instruments”, *supra* note 11 at 303.

<sup>64</sup> See Burelli, *supra* note 53.

<sup>65</sup> Val Napoleon, “Indigenous Legal Perspectives and Drafting Impact Benefit Agreements” in Arielle Dylan & Bartholomew Smallboy, eds, *Impact Benefit Agreements*

realities, the next section outlines the extant public funded institutional research ethics landscape in Canada and calls attention to its specific elaboration on “Research Involving Aboriginal Peoples”.

#### IV. PART III: PUBLICLY FUNDED RESEARCH ETHICS LANDSCAPE IN CANADA

##### (a) The Tri-Council Policy Statement

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS or the Policy)<sup>66</sup> governs publicly funded research in Canada. The Tri-Council consists of Canada’s three national agencies: The Social Sciences and Humanities Research Council of Canada (SSHRC), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Canadian Institutes of Health Research (CIHR), which typically fund public research at post-secondary institutions in Canada. All researchers and institutions that receive funding from any of the three agencies are required to comply with the Policy pursuant to an agreement between the institution and the agencies as facilitated by each institution’s Research and Ethics Board (REB). The TCPS describes the basic requirements on the review, oversight and conduct of research involving humans. Informed by, and in compliance with, international human rights norms, the Policy helps researchers, participants and institutional administrators understand and apply ethical standards to the research process. The Policy covers procedure on topics such as informed consent, privacy, confidentiality and conflict of interest.

Central to the Policy is respect for human dignity. Research is required to be conducted in a manner that is “sensitive to the inherent worth of all human beings”.<sup>67</sup> This value is expressed through three core principles: a) respect for persons; b) concern for welfare; and c) justice, which form an integral part of the guidelines on conducting research involving Aboriginal Peoples. The goal of the Policy is to help protect research participants while balancing the legitimate goals of research. Similar to the evolutionary principles of the Bonn Guidelines, the Policy is not meant to be static, but intended to be evolving in accordance with the dynamism of social reality, values and research exigency.<sup>68</sup>

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[forthcoming 2017]; David Milward, *Aboriginal Justice and the Charter: Realizing a Culturally Sensitive Interpretation of Legal Rights* (Vancouver: UBC Press, 2012); Law Commission of Canada, *Indigenous Legal Traditions* (Vancouver: UBC Press, 2007); Friedland & Napoleon, *supra* note 54.

<sup>66</sup> Canada, Canadian Institute of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri Council Policy Statement—Ethical Conduct for Research Involving Humans* (Ottawa, 2014) [TCPS or the Policy].

<sup>67</sup> *Ibid* at 6.

<sup>68</sup> Canada, Interagency Advisory Panel and Secretariat on Research Ethics, *Issues and Options for Revisions to the Tri-Council Policy Statement on Ethical Conduct of Research*

**(b) Historical Context of the Tri-Council Policy Statement**

The TCPS was first released in 1998, about the time of the *Royal Commission on Aboriginal Peoples* with the commitment to regularly update the Policy in response to changes in societal values.<sup>69</sup> In 2003, an independent advisory panel on research ethics made a recommendation to develop guidelines on research involving Aboriginal Peoples.<sup>70</sup> Following extensive dialogue with Aboriginal organizations and representatives, the provisions of the Policy were revised and adopted in 2009, reflecting Aboriginal research and research ethics.<sup>71</sup> The existing guidelines contain both mandatory requirements as well as permissive or exhortatory guidelines for researchers and institutions.<sup>72</sup> The Tri-Council Policy devotes a chapter to the ethical conduct of research involving the First Nations, Inuit and Metis Peoples of Canada. The current TCPS – TCPS2, adopted in 2014, reflects no change in the latter chapter.<sup>73</sup> The Policy recognizes the distinctive status of Aboriginal Peoples, acknowledges their unique histories, cultures and traditions.

As indicated earlier, external persons or entities largely conduct most research involving Aboriginal Peoples, a situation that touches the frayed nerves of Aboriginal colonial relations predominantly characterized by mistrusts and inequitable power relations. Not only do Aboriginal Peoples decry being perennial subject of research, they protest and insist that the manner in which the research is conducted does not reflect Aboriginal views. As well, the results and benefits of research may not inure to Aboriginal communities. In the exact words of the FNIGC, “First Nations have often complained that they have been the focus of too much research (i.e. “Researched to Death”), that research projects are too often conducted by non-First Nations people, that research results are not returned to communities, and that the research does not benefit First Nations people or communities”.<sup>74</sup> In response to these issues, Chapter 9 of the Policy serves to better inform research practices involving Aboriginal Peoples, by taking into account the risks involved in engaging a vulnerable community. This chapter serves to encourage respect and collaboration between researchers and Aboriginal research participants through a list of ethical obligations. The document resulted from collaborative efforts of the three agencies, with special recognition of “the CIHR and its Institute of Aboriginal Peoples’ Health [which] engaged in extensive dialogue with community partners to develop the *CIHR Guidelines for Health Research Involving Aboriginal People*.

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*Involving Humans (TCPS): Section 6: Research Involving Aboriginal Peoples*, (Ottawa, 2008) at 3.

<sup>69</sup> *Ibid.*

<sup>70</sup> *Ibid* at 3.

<sup>71</sup> *Ibid* at 1.

<sup>72</sup> TCPS or the Policy, *supra* note 66 at 11.

<sup>73</sup> *Ibid*, ch. 9.

<sup>74</sup> FNIGC, *supra* note 3.

The CIHR Guidelines remain an important source of additional guidance for health research involving Aboriginal Peoples in Canada”.<sup>75</sup> The two remaining agencies of the Tri-Council, namely the SSHRC and NSERC have also developed their own respective guidelines for research relating to Aboriginal Peoples and issues.

**(c) Guidelines for Conducting Research Involving Aboriginal Peoples**

The policy governing Aboriginal research can be divided into several components. It contains guidelines, which govern engagement with Aboriginal communities, benefit sharing of the results and additional provisions to help implement the guidelines. Under the framework, researchers are required to engage with Aboriginal communities where research is likely to affect the welfare of the community.<sup>76</sup> The nature of community engagement is determined by the researcher and the community. For example, research may require approval by a designated body in the community or simply require consent of individuals participating in the research. Researchers are required to advise the REB on how they have engaged or intend to engage the relevant community.<sup>77</sup>

In addition to engaging with the community, researchers are required to be informed of the relevant customs and traditions that are pertinent to the community affected by the research.<sup>78</sup> For instance, Aboriginal customs may limit certain sacred knowledge shared with researchers from being publicly shared. Any restrictions imposed on traditional or sacred knowledge are required to be integrated into a research agreement between the community and the researcher.<sup>79</sup> The purpose of the research agreement is to set out terms of the research, including the scope of engagement with both sides. It helps to clarify mutual expectations. At a minimum, the Policy requires the agreement to specify how individual consent will be secured; how research benefits will be shared; how IP rights, if applicable, will be respected.<sup>80</sup> These elements of the agreement are subject to REB approval and the agreement would precede the collection of data.

Furthermore, the Policy points out that research should benefit the community. Where possible, research should be relevant to the needs and priorities of the community,<sup>81</sup> as is the case with the RHS mentioned above pursuant to the FNIGC. Research should have the potential to produce a value to the community and its members, such as recognizing the contributors and returning results to the community. Research should also strengthen capacity of the community, allowing for reciprocal transfer of knowledge.<sup>82</sup> Capacity

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<sup>75</sup> TCPS or the Policy, *supra* note 66, ch. 9.

<sup>76</sup> *Ibid*, art. 9.1.

<sup>77</sup> *Ibid*, art. 9.10.

<sup>78</sup> *Ibid*, art. 9.8.

<sup>79</sup> *Ibid*, art. 9.8.

<sup>80</sup> *Ibid*, art. 9.11.

<sup>81</sup> *Ibid*, art. 9.13.

building can occur in many ways, for example, through the hiring of local Aboriginal research assistants and training community members in research methods to enhance skills within the community. As with FNIGC-RHS principles, where possible, Aboriginal Peoples could be grant holders for funded research.

The Policy contains additional provisions to encourage collaboration and participatory approaches between researchers and the community, where possible.<sup>83</sup> Collaboration may involve working together to define the project, collecting and interpreting the data and producing the final product. If collaborative approaches are adopted, they should be outlined in the research agreement. Overall, there is a marked shift from the obsolete practice of merely conducting research on Aboriginal Peoples to doing research by and with Aboriginal Peoples. The latter approach emphasizes Aboriginal Peoples' participation, partnership and collaboration with researchers in ways that are readily reconcilable with the OCAP principles mentioned above. As a related matter, the Policy recognizes progressive involvement of Aboriginal personnel and communities in promoting research ethics on Aboriginal research. Therefore, the policy "is not intended to override or replace ethical guidance offered by Aboriginal peoples themselves".<sup>84</sup> The next section identifies gaps in the TCPS relating to ABS and conjectures on how such gaps could be ameliorated.

## **V. PART IV: IDENTIFYING AND PLUGGING GAPS IN THE TRI-COUNCIL POLICY IN RELATION TO ABS**

The current research ethics landscape in Canada requires several changes in order to comply with the global ABS regime pursuant to the NP. However, it bears repeating that the NP is limited only to research relating to access and utilization of genetic resources and associated traditional knowledge with ultimate focus on enhancing the conservation of biological diversity, whereas research dealing with Aboriginal Peoples transcends ABS issues. In this section, we outline key areas where the Policy could be modified to comply with the NP. First, both documents differ in their scope. Second, the Tri-council Policy is sensitive to the access provisions of the NP but it does not comply with the benefit sharing obligations of the NP. Third, the Policy requires additional provisions to ensure compliance with the ABS scheme, which is mandated by the NP. We discuss each of these areas in further detail below.

### **(a) Scope**

The scope of the Policy will need to be expanded to comply with the NP and reflect specific sensitivity to ABS principles. When conducting research with

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<sup>82</sup> *Ibid*, art. 9.14.

<sup>83</sup> *Ibid*, art. 9.12

<sup>84</sup> *Ibid*, ch. 9.

Aboriginal Peoples, research ethics review focuses on research involving the participation of Aboriginal Peoples.<sup>85</sup> Scope of participation in humanities and social sciences research differs from research in the biomedical sciences, including health sciences in which Aboriginal and other human persons can be subjects of research and bearers of the primary risk of the research through various forms of participation including donation of human genetic material, which is the focus of Chapter 2 of the Policy and not the direct concern of the present analysis. As already mentioned, the CIHR has *Guidelines for Health Research Involving Aboriginal People*, which may include the use of personal or communal information from Aboriginal Peoples or the use of their human genetic materials derived from their biological samples, as an aspect of participation in research.

However, the Policy does not offer direct ethical guidance on the use of non-human genetic resources derived from Aboriginal communities, which are subject to the NP.<sup>86</sup> The meaning of participation of Aboriginal Peoples would include where they voluntarily contribute genetic resources and their traditional knowledge or related information to the research. The problem is that more often such information is taken without their free PIC, which is a principle recognized both under the Policy and the NP. However, given the increased controversy regarding dealings with genetic resources and the phenomenon of biopiracy, the Policy may need to directly address those interrelated subject matters taking into account the inbuilt flexibilities of the NP that incorporate customary protocols as aspects of legal tradition of specific ILC. In sum, to fully comply with the NP or its general framework, REB review pursuant to the Tri Council Policy may need to be extended to robustly and specifically include research involving the use of non-human genetic resources, as well as traditional knowledge associated with such genetic resources. These changes are critical in ensuring fairness and equity in the utilization and the benefits of genetic resources, especially when the resources originate from Aboriginal lands.

#### **(b) Access Obligations**

The Tri-Council Policy could be said to be sensitive to the access obligations of the NP. According to the NP, access to genetic resources and associated traditional knowledge held by ILCs are subject to PIC.<sup>87</sup> This aligns with the Policy's provision on consent, which must be "free, informed and ongoing" throughout the research process.<sup>88</sup> REB review requires researchers to provide prospective participants with full disclosure on all information available for making an informed decision on whether to grant consent.<sup>89</sup> In addition,

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<sup>85</sup> *Ibid*, art. 2.1.

<sup>86</sup> NP, *supra* note 12, art. 3.

<sup>87</sup> *Ibid*, arts. 6 and 7.

<sup>88</sup> TCPS or the Policy, *supra* note 66 at 25.

<sup>89</sup> *Ibid*, art. 3.2.

researchers are required to document proof of consent, whether through obtaining a signed consent form or another appropriate means of consent that passes the ethical threshold.

The NP treats ILCs with special consideration and imposes additional obligations when accessing traditional knowledge associated with genetic resources.<sup>90</sup> Parties and, by extension, researchers are required to take into account the customary laws of the community, community protocols and help in their development.<sup>91</sup> Stakeholders must also help develop “minimum requirements for mutually agreed terms” as well as assist with building the capacity of ILCs.<sup>92</sup>

The Policy meets most of the requirements above, although it does not mandate some of the practices, as outlined below. The Policy advises researchers to be informed about and respect the relevant customs and practices that apply to the particular Aboriginal community.<sup>93</sup> The language is exhortatory and permissive unlike the wording of the NP, which is stronger in mandating such an activity. The Policy does not explicitly advise stakeholders to help develop community protocols but advises researchers to help support capacity building in ILCs<sup>94</sup> and develop minimum requirements for mutually agreed terms through the use of research agreements.<sup>95</sup> However, whether or not Canada accedes to the NP, there is a compelling case for Aboriginal Peoples to insist upon their own customary laws and protocols on ABS and to hold researchers to the prescriptions of those Indigenous legal regimes, which are already the practice.

### **(c) Benefit Sharing Obligations**

Unlike the NP, the Policy does not mandate benefit sharing of genetic resources. Nor does it mandate benefit sharing over the uses of traditional knowledge associated with genetic resources, derived from ILCs. Rather, the Policy denotes guidelines for benefit sharing.<sup>96</sup> This is contrasted with the strong language of the NP, which mandates benefit sharing.<sup>97</sup> Despite the variation in language, the Policy, complies with the obligation to establish mutually agreed terms (MAT) for ABS. The process described in Article 9.11 of the Policy closely resembles the obligations in Article 5.1 of the NP for establishing MAT over the use of genetic resources or traditional knowledge associated with genetic resources derived from ILCs. Based on Article 9.11 of the Policy, researchers are required to set out “the terms and undertakings of both the research and the

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<sup>90</sup> NP, *supra* note 12, art. 12.

<sup>91</sup> *Ibid*, art. 12.

<sup>92</sup> *Ibid*, art. 12.

<sup>93</sup> TCPS or the Policy, *supra* note 66, art. 9.8

<sup>94</sup> *Ibid*, art. 9.14.

<sup>95</sup> *Ibid*, art. 9.11.

<sup>96</sup> *Ibid*, art. 9.13.

<sup>97</sup> NP, *supra* note 12, art. 5.



community” in a research agreement before participants are recruited. The purpose of the agreement is to clarify and confirm mutual expectations on issues such as benefit sharing or royalties flowing from IP and protection of restricted knowledge.

The Policy is less specific than the NP in describing the monetary and non-monetary methods for benefit sharing. The Annex to the NP lists various examples of how benefits can be shared. The Policy also describes the use of monetary or non-monetary benefit sharing methods as incentives to research, but the Policy is not as detailed in providing various examples of benefit sharing mechanisms (i.e. joint ventures, social recognition, milestone payments) as the NP.<sup>98</sup> This is not a flaw in and of itself to the extent that NP adopts essentially a market economic approach to incentivize the conservation of biodiversity, while the Policy is conceivably open to accommodating many other considerations. As well, it is also amenable to an expansive conceptualization of benefits arising from Aboriginal-related research as it recognizes that benefits transcend economic and market considerations.

#### **(d) Benefit Sharing in Transboundary Context**

There are two types of situations for benefit sharing that the Tri-Council Policy is silent on. It does not make reference to benefit sharing in situations where research involves the utilization of genetic resources in a transboundary situations or where it is impossible to obtain PIC. On the other hand, the NP provides for transboundary cooperation where genetic resources and associated traditional knowledge are found in places that traverse national boundaries, thus shared by more than one country or more than one ILC in several countries. Cooperation is relevant for ensuring that benefits are shared in a fair manner. In a transboundary situation or where it is impossible to obtain PIC, the NP provides for a global multilateral benefit sharing mechanism, which is intended to be the repository of the benefits from the users as a form of trust for providers. In order to comply with these obligations, the Policy may need to provide clarity on the issue of benefit sharing in transboundary situations. This would require a framework to support benefit sharing mechanisms among the 73 Aboriginal nations of Canada at a Canadian national level akin to the global benefit sharing mechanism for transboundary genetic resources pursuant to the NP. Some jurisdictions that have advanced ABS regimes (compared to Canada) have developed centralized trust-like benefit framework from which *all* local knowledge and genetic resource holders can draw.<sup>99</sup> In his contribution to the second Focus Group on ABS organized by the ABS Canada research initiative, Aboriginal legal scholar, professor Larry Chartrand, argues that Aboriginal legal traditions have protocols for negotiating interests that cut-across Aboriginal cultural and resource boundaries. He suggests that Canada should learn from such traditions in developing a national policy on ABS.<sup>100</sup>

<sup>98</sup> TCPS or the Policy, *supra* note 66, art. 9.13.

<sup>99</sup> For example, India, Namibia, Brazil, Peru, etc.

**(e) Compliance Mechanism**

The NP provides directions for compliance with the ABS scheme but in prescriptive and less proactive terms. In contrast, the Policy does not include such compliance measures as part of the research ethics review process. The NP requires parties to ensure that genetic resources and the associated traditional knowledge utilized within their jurisdiction are accessed upon PIC and on the bases of MAT.<sup>101</sup> In addition, under the Protocol, the use of genetic resources must be monitored through designated checkpoint(s) and supported by an internationally recognized certificate of compliance.<sup>102</sup> The purpose of the checkpoint is to not only monitor compliance but to enhance transparency on the use of genetic resources, by collecting relevant information such as the source of the genetic resource, PIC, and the establishment of MAT; as well as to report and monitor changes in the originally disclosed use(s) of genetic resources. To meet these requirements, the Policy may need to implement changes to the REB review process. There is need to take measures to not only ensure that researchers' attention is drawn to the ABS requirements and appropriate domestic implementing legislation. That way, researchers are fully conscious of their obligations. They should also be aware that the consequences of non-compliance involve additional sanctions to those naturally resulting from the REB process. In addition, REB may have to create an obligation on researchers to proactively disclose subsequent uses of genetic resources that are different from originally disclosed uses. In trying to align research ethics process with the NP, care should be taken, however, so as not to undermine the overarching principles of the ABS process, notably the ease of use and practicability, which are among the 8 pillars of the Bonn Guidelines incorporated into the NP. This would require a delicate balancing and/or administrative calibration of interest to ensure that ABS is fair to the needs of Aboriginal Peoples as well as advance and not scuttle the objectives of research.

To expedite the monitoring process, REB could assist in enhancing the checkpoint process. Given that an application seeking permission to use genetic resources for research can be disclosed directly in the REB review process for approval, REB could ensure that researchers secure access permits as evidence that genetic resources and associated traditional knowledge have been accessed in accordance with PIC and MAT. Under the NP, the issued permit would comply with the use of an internationally recognized certification of compliance, if it contains information at the minimum detailing: issuing authority, date of issuance; the provider; unique certificate identifier; recipient of PIC; subject matter or genetic resource in question that is the subject of PIC; confirmation

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<sup>100</sup> See Chidi Oguamanam, Chris Koziol & Freedom Kai-Phillips, "ABS Canada Ottawa Focus Group Report" (2016) *ABS Canada*, online: <<https://www.abs-canada.org/portfolio-view/ottawa-focus-group-report/>> (accessed July 12, 2017).

<sup>101</sup> NP, *supra* note 12, art. 15.

<sup>102</sup> *Ibid*, art. 17.

regarding MAT; information on commercial and or non-commercial uses of the genetic resources.<sup>103</sup> On a practical note, these would seem to be an onerous responsibility for an institutional REB. At the very least, however, REBs must ensure that before they sign off on a relevant research ethics application, such researchers undertake to comply with these expectations and work with the applicable Aboriginal Peoples to fully account for the procurement, monitoring and the use of genetic resources.

Without being exhaustive, we have so far identified a few key areas where the Policy and the global ABS framework diverge. In order to bring Canadian research ethic protocol within the extant international obligation on ABS pursuant to the NP, the Policy, especially the aspect dealing with Aboriginal-related research, requires deliberate revisions. In the next section, we examine how advances in biotechnology present yet another challenge to the effective realization of ABS. We also shed some light on the ways around such challenges for effective realization of ABS by Indigenous Peoples and local community stakeholders.

## **VI. PART V: CURRENT ABS REGIME AND ADVANCES IN BIOTECHNOLOGY**

Aside from the gaps in existing Canadian ethics landscape as it relates to ABS over research dealing with Indigenous Peoples, advances in modern biotechnology proceed with increased sophistication capable of escalating those gaps. Because technologies are naturally ahead of the law, the question is whether the current global ABS regime has effectively pre-empted these technological advances. Our focus in this section is on one of the symbolic representations of the trend in biotechnological sophistication in which the use of genetic resources and associated traditional knowledge are implicated, namely digital DNA. The latter raises new challenges for ensuring compliance under the ABS regime. Of concern is whether digital genetic resources are pre-empted by the NP and therefore subject to its elaborate provisions on ABS. Digital genetic resource in general and, specifically for our purpose, digital DNA in particular symbolize the increasing role technology plays in the acquisition, transformation, control and utilization of genetic resources, including of course those that originate from Aboriginal communities. The question is whether digital DNA is subject to the same research ethics obligations that apply to dealings in tangible genetic resources.

### **(a) The Concept of Digital DNA**

The last few decades have witnessed widespread digitization of data. Tangible, hard copies of data, including those derived from genetic resources, can now be transformed into digital soft copies. Data transformation is widespread in the scientific realm, especially in the context of genetic data.

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<sup>103</sup> *Ibid*, art. 17.4.

Genetic information in the form of DNA sequences can be digitally stored, reproduced, and manipulated. DNA can be shared and accessed easily for research. Digital DNA is particularly relevant for conducting research in synthetic biology, genomics, genetic engineering, genetic epidemiology, etc.

Synthetic biology is a multidisciplinary field at the interface of engineering and molecular biology. It attempts to construct novel DNA parts that do not exist in nature or redesign existing biological systems using modular DNA parts.<sup>104</sup> Synthetic biologists consider biological systems as a combination of genetic parts that are thought to be predictable and well characterized.<sup>105</sup> These parts can be rearranged and combined in novel ways to form new and complex systems or modify existing properties of living organisms.

By redesigning biological systems, advances in synthetic biology are helping address challenges in agriculture, medicine and the environment. A number of synthetic biology researchers are finding new ways to produce medicines, materials and food. For example, researchers have designed and produced bacteria that can detect and measure environmental contaminants such as heavy metals, explosives or pesticides.<sup>106</sup> Researchers have also helped develop drought resistance plants that consume less water, opening up doors for crop improvement.<sup>107</sup> These plants are embedded with redesigned biological parts not found in nature. Digital DNA makes it easier to conduct research. Rather than sourcing genetic sequences in nature, researchers can use online databases to download DNA sequences for free, as the cliché goes, with a click of a button. These sequences can be customized and then ordered from commercial laboratories to conduct research, allowing entire genomes or genes to be constructed from scratch. As DNA synthesis and sequencing technologies become cheaper, it may be faster to synthesize certain DNA sequences than to find them in nature.

#### **(b) Nagoya Protocol, Digital DNA, ABS and Biopiracy**

Despite the obvious advantages of using digital DNA for research, it raises concerns for biopiracy. Users can benefit from genetic resources or local knowledge available on the web without necessarily being obliged to share the benefits derived from using the online data. The NP and the CBD do not explicitly address the concerns raised by synthetic biology and particularly digital

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<sup>104</sup> Antoine Danchin & Victor de Lorenzo, “Synthetic Biology: Discovering New Worlds and New Words: The New and Not So New Aspects of This Emerging Research Field” (2008) 9 *EMBO Reports* 822.

<sup>105</sup> Paul Oldham, Stephen Hall & Geoff Burton, “Synthetic Biology: Mapping the Scientific Landscape” (2012) *PLOS One* e34368, online: <<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0034368>>.

<sup>106</sup> Harald König et al, “Synthetic Genomics and Synthetic Biology Applications Between Hopes and Concerns” (2013) 14:1 *Current Genomics* 11.

<sup>107</sup> Elena Fesenko & Robert Edwards, “Plant Synthetic Biology: A New Platform for Industrial Biotechnology” (2014) 65:8 *J Experimental Botany* 1927.

DNA. These documents were drafted with tangible genetic resources in mind.<sup>108</sup> However, the issue of digital DNA has been raised in the negotiations leading up to the NP. The fundamental question is whether virtual genetic information requires new considerations for ABS or whether it is subject to the standard ABS framework to resolve conflicts and controversy surrounding the use of this new technology. Below, we outline some of the challenges raised by digital DNA in regard to ABS.

(i) *Defining the Scope of Genetic Resources*

Under the NP, the status of digital genetic information is unclear. The current provisions governing the transfer, use and handling of genetic information are inadequate for digital genetic resources. While the NP does not define genetic material, CBD defines them as, “any material of plant, animal, microbial or other origin containing functional units of heredity.”<sup>109</sup> Whether the definition of genetic material will be interpreted broadly enough to include digital genetic information is uncertain. These uncertainties raise analogous concerns regarding whether derivatives of genetic resources, even of traditional knowledge, are subject to ABS requirements.<sup>110</sup> While the FAO International Treaty’s ABS framework applies to genetic resources that are kept in the form received from the provider, the Fridtjof Nansen report recommends using a “broad” definition of genetic resources to maintain a “dynamic” understanding of the concept.<sup>111</sup>

The World Intellectual Property Organization recently commissioned a study on patent disclosure requirements for utilization of genetic resources and traditional knowledge, which is part of the trigger for ABS claims.<sup>112</sup> The study

<sup>108</sup> Margo A Bagley, “Digital DNA: The Nagoya Protocol, Intellectual Property Treaties and Synthetic Biology,” (2015) *Wilson Centre*, online: < [https://wilsoncenter.org/sites/default/files/digital\\_dna\\_final\\_0.pdf](https://wilsoncenter.org/sites/default/files/digital_dna_final_0.pdf) > .

<sup>109</sup> CBD, *supra* note 14 at 3.

<sup>110</sup> The SCBD support the idea that derivatives are subject to ABS. See Lyle Glowka, “The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization” (Presentation delivered at the Ad-Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond the areas of national jurisdiction, 31 May-3 June 2011), online: < [http://www.un.org/Depts/los/biodiversityworkinggroup/4th\\_wg\\_cbd\\_presentation.pdf](http://www.un.org/Depts/los/biodiversityworkinggroup/4th_wg_cbd_presentation.pdf) > ; Ryo Kohsaka notes that while the ABS requirements in the NP do not expressly refer to the term “derivatives,” the concept could be seen to complement the definition of “utilization of genetic resources”: See Ryo Kohsaka, “The Negotiating History of the Nagoya Protocol on ABS: Perspective from Japan” (2012) 9:1 (日本知財学会誌), 61-62, online: < [https://www.ipaj.org/english\\_journal/pdf/9-1\\_Kohsaka.pdf](https://www.ipaj.org/english_journal/pdf/9-1_Kohsaka.pdf) > .

<sup>111</sup> Fridtjof Nansen Institute, “The Concept of “Genetic Resources” in the Convention on Biological Diversity and How It Relates to a Functional International Regime on Access and Benefit Sharing” (2010), online: < <https://www.cbd.int/docmeetingsabsabswg-09informationabswg-09-inf-01-en.pdf> > .

<sup>112</sup> See WIPO, “Patent Disclosure Requirements”, *supra* note 35.

examines the kind of relationship or link between subject matter utilized and the nature of claimed invention that could warrant patent disclosure requirement and ultimately ABS claims. The study identifies three broad categories that link genetic resources and associated traditional knowledge, and the invention claimed under patent application. The invention must: i) include the *utilization* of genetic resource or traditional knowledge; or ii) be *derived* from genetic resources or traditional knowledge; or iii) be *based* on genetic resources or traditional knowledge or “directly” based on them”.<sup>113</sup> The study notes that the NP adopts a broad definition of utilization of genetic resources pursuant to Article 2(c) which includes “research and development; biochemical composition of genetic resources; and application of biotechnology”.<sup>114</sup>

From the WIPO study, it is clear that majority of national laws or jurisdictions that have adopted patent disclosure requirements in the context of genetic resources and traditional knowledge favour a broad understanding of genetic resources and their various transformations, which arguably includes the context of digital DNA, lending them to ABS claims. But adopting a broad definition results in other concerns as discussed below.

*(ii) Obtaining Access*

If the scope of the NP is broadened to include digital DNA, the access provisions will be difficult to implement. Based on Article 6 of the NP, users of genetic resources are required to seek PIC to access genetic resources. This implies knowing the origin of genetic resources. Some countries such as China and Brazil require patent applications to include the origin of genetic resources used.<sup>115</sup> In the case of digital DNA, it may not be feasible to identify the origin of genetic resources and obtain consent. Many genetic databases do not provide a clear and traceable pathway to the origin of the genetic material. As a result, researchers may download DNA sequences without having information about the origin of the sample. Also, the synthetic biological process of constructing novel DNA parts that do not exist in nature or redesigning existing biological systems using modular DNA parts results in de-linking genetic materials from any credible or easily traceable sources or their origin, which changes the access dynamic.

*(iii) Benefit Sharing*

The NP requires the benefits arising from the use of genetic resources to be shared with the provider. Without information available about the origin of a digital DNA sequence, it would not be feasible to accurately identify the beneficiaries. For instance, if a genetic sequence found on the web exists in

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<sup>113</sup> *Ibid* at 35.

<sup>114</sup> *Ibid*.

<sup>115</sup> Queen Mary Intellectual Property Research Institute, “Report on Disclosure of Origin in Patent Applications” (2004), For the European Commission, DG Trade, online: <[http://trade.ec.europa.eu/doclib/docs/2005/june/tradoc\\_123533.pdf](http://trade.ec.europa.eu/doclib/docs/2005/june/tradoc_123533.pdf)> .

various organisms found around the world, this raises challenges in terms of which country should have a right over the sequence. Another practical matter is determining the quantity of the contribution of a particular sequence to a product that could trigger benefit sharing.

*(iv) Compliance*

The NP also requires the use and access of genetic resources to be monitored through appropriate checkpoints. By using digital DNA, it is possible to bypass this requirement because sequences can easily be accessed and downloaded from online public databases. Developing and enforcing local laws to ensure compliance with the elements of the ABS regime in the context of digital DNA could go beyond the means, expertise, and resources available of many developing countries and ILCs. With widespread availability of genetic information online, the possibility of getting caught is slim. Local compliance will be difficult without international consensus on how DNA sequences accessed from databases are to be regulated.

The concerns raised by synthetic biology have led to the formation of the International Civil Working Group in Synthetic biology to propose recommendations for the NP. The group suggested extending ABS protection to cover digital genetic sequences and products derived from natural sequences using synthetic biology tools.<sup>116</sup> If digital DNA is excluded from the NP, the status of virtual genetic resources will be left up to the national legislation that implements ABS.

**(c) Practical Concerns for Research**

On one hand, digital DNA raises concern for biopiracy because of the possibility to bypass ABS obligations. If providers of genetic resources believe that they can be bypassed, they may oppose public sharing of results in the research agreement and erect barriers to restrict access. On the other hand, extending the ABS regime to include digital DNA raises practical concerns for researchers. If researchers have to engage in costly transactions to access genetic sequences on the web, it may limit access to data and impede the development of new products not to mention undermining the core principles of ABS as articulated in the Bonn Guidelines. Speed and accessibility are crucial for advancing synthetic biology research. Benefit sharing rules for digital DNA may be difficult to impose while attempts to undermine access would weaken open and collaborative culture of research.<sup>117</sup>

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<sup>116</sup> The International Civil Society Working Group on Synthetic Biology, "A Submission to the Convention on Biological Diversity's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) on the Potential Impacts of Synthetic Biology on the Conservation and Sustainable Use of Biodiversity" (2011), online: <https://cbd.int/doc/emerging-issues/Int-CivilSoc-WG-Synthetic-Biology-2011-013-en> > .

<sup>117</sup> Arti Rai & James Boyle, "Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons" (2007) 5:3 *PLoS Biology* e58.

Once information is publicly available on the web, attempt to impose restrictions is like forcing the genie inside the bottle. In this case, such attempt would have the nuisance effect as a barrier to innovation. Yet, given the fact that one of the overarching *raison d'être* of ABS is to incentivize the contributions of ILCs and their traditional knowledge, the illusive nature of digital DNA requires proactive initiatives to support and not alienate ILCs' contributions to global biodiversity.

As mentioned above, the NP encourages transboundary cooperation over dealings with genetic resources that exist *in situ* within the territory of multiple parties as well as where traditional knowledge and associated genetic resources are shared by multiple ILCs across State Party boundaries. Article 10 encourages Parties to develop modalities for setting up global multilateral benefit sharing mechanism aimed at fair and equitable sharing of benefits derived from utilizing genetic resources and traditional knowledge associated with genetic resources in transboundary situations. Similarly, the FAO International Treaty in Articles 10-13 makes elaborate provisions for a global centralized multilateral system of ABS over genetic resources for food and agriculture in its common pool. Within the International Treaty's multilateral framework, access to PGRFA in the common pool and equitable benefit sharing arising from their use are to be prioritized. Not only would this help support information exchange, and technology transfer, but it would also build capacity in developing countries, and by extension ILC agro-ecological practices. This is in recognition that ILCs in developing countries and their counterparts elsewhere are mainly the sources and stewards of the global pool of premium genetic resources in the multilateral system. Given the decentralized and virtual nature of digital DNA and the malleability of information around its application, the framework for transboundary cooperation and the global multilateral benefit sharing mechanism under the NP and the International Treaty provide analogous bases to support the extension of the ABS to digital DNA.

## VII. CONCLUSION

In the last several decades, research ethics landscapes have continued to change globally, including in Canada. Attempts have been made to address the historically troubled relationship between Aboriginal Peoples of Canada and research communities and other entities involved in research related activities concerning Aboriginal Peoples. Not only has the Tri-Council Policy developed special guidelines dealing exclusively with research involving Aboriginal Peoples, the latter have also been proactive in their engagement with researchers by developing their own protocols and principles in specific research contexts that have implications for Aboriginal research in several other contexts in general.

Lately, the NP symbolizes the highpoint of lingering international efforts to recognize the role of ILCs and their traditional knowledge in the conservation of genetic resources and biological diversity. Like no other instrument, the NP specifies detailed strategy via the principle of fair and equitable ABS to balance



the rights of all stakeholders, including ILCs, in the use and conservation of biological resources and biological diversity. It has opened new opportunities to further develop and strengthen current research ethics landscape relating to Aboriginal Peoples in Canada, in order to align them with some emphasis on the ABS imperative. In this Article, we have identified some gaps in the current research ethics policy framework in Canada regarding Aboriginal Peoples that are required to bring it in sync with the emergent thinking on ABS. As a practical matter, both regimes could be mutually complementary.

Both the extant research ethics regime relating to Aboriginal Peoples and the current NP-inspired ABS system do not directly account for transformations in biotechnology, with specific regard to digital DNA as a resourceful research asset. Technological transformations in biotechnology enable genetic information in the form of DNA sequences to be stored digitally. Digital DNA offers a malleable opportunity to manipulate and adapt the DNA sequence, especially in synthetic biology whereof it is possible to construct non-naturally occurring novel DNA or even to use modular DNA parts to construct or redesign existing biological formation.

With apparent focus on corporeal genetic resources, the NP does not directly pre-empt the virtual contexts for the application and malleability of digital DNA as a resourceful data, despite the difficulty of linking such data to a specific source. As well as posing a problem to the NP's ABS system, the idea of digital DNA also presents a challenge to current policy framework on Aboriginal research pursuant to the Tri-Council ethics protocol. Neither the NP nor the Policy on Aboriginal research pre-empted the virtualization of research data in general or the notion of digital DNA in particular. However, both regimes recognize the evolutionary nature of research and do not intend that their operating principles remain static. Specifically, Chapter 9 of the Policy on Aboriginal research recognizes the necessity for continued evolution and periodic revisions of the document. In that regard, there is sufficient basis for expansive interpretation of genetic resources to include its various rendition, including digital DNA forms. And conceivably, incorporating the uses of digital DNA into the ABS regime in ways that entitle Aboriginal communities to benefit sharing is consistent with NP's provision for a global multilateral benefit sharing mechanism. It is also consistent with NP's transboundary cooperation in regard to transboundary genetic resources and traditional knowledge shared by multiple ILCs in more than one State Party or where it is difficult to obtain consent for the use of genetic resources from any entity. Digital DNA can be likened to transboundary genetic resources. Also, they are akin to the categories of genetic resources regarding which it is difficult to obtain free PIC for their use. In some ways, that approach draws parallel from the multilateral system of ABS under the FAO International Treaty. In adjusting or re-imagining the current Canadian research ethics policy on Aboriginal research to the ABS imperative under the NP, there is also an opportunity to explore the challenge posed by

transformations in biotechnology, in this case, as typified by digital DNA, and their ramification for ABS.

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