THE Information Accountability Foundation

COLLABORATIVE POLICY INNOVATION

Report for the Comprehensive Assessment Oversight Dialog: Canadian Ethical Data Review Boards Project

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Introduction

The Information Accountability Foundation (IAF) received a grant from the Office of the Privacy Commissioner (OPC) to explore oversight over data processing assessment processes (Oversight Grant). The Oversight Grant required the IAF to explore primarily whether attributes attributed to Research Ethics Boards (REBs) could enhance the trustworthiness of comprehensive assessments conducted by business, and secondarily oversight of the assessment process by accountability and regulatory agencies (Oversight Project).

Privacy impact assessments (PIAs) have been a standard part of privacy management since the Federal Privacy Commissioner and information commissioners from British Columbia and Alberta published accountability guidance in 2012. The continued acceleration of advanced analytics has led to assessments that go well beyond legacy fair information practices to a determination of whether a processing that is beyond the common knowledge of people would be considered legitimate, reasonable, and appropriate. The Oversight Grant is a complement to a grant the OPC made to the IAF in 2016 to explore a common set of elements for assessments by organizations that would determine whether processing was reasonable, legitimate, and appropriate because it was legal, fair and just (Assessment Grant). After three meetings with business stakeholders, the IAF created an assessment framework (Canadian Assessment Framework). The IAF then held a meeting that included enforcement agencies, academics, and privacy advocates as well as business stakeholders to review the Canadian Assessment Framework (Assessment Project). Many of those participants raised issues of trustworthiness about assessments conducted solely by a business. They suggested a process similar to REBs might add trust to the assessment process. This recommendation was included in the report filed with the OPC in February 2017 and was the basis for IAF seeking the Oversight Grant.

Oversight Project Report Summary of Findings

As they relate to REBs
- REB reviews are required for scientific research in Canada that is conducted directly on people. That research includes but is not limited to clinical research.
- REBs are governed by the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#) (TCPS). The 210-page TCPS covers all aspects of how REBs are structured and operate. The TCPS creates a commonality of process in REBs at institutions throughout Canada. The guidance is based on three core principles: (1) respect for persons, (2) concern for welfare, and (3) justice.
- The TCPS covers both the manner in which a review is conducted and the construction of the body that will conduct the review. It also establishes the independent status of the REB within the institution.
- The rigor of a review is proportional to risk to people associated with a research proposal.
- A review is conducted in a manner that is independent of the researcher but is not typically independent of the parent institution. The institution, in most cases, is the home for both the researcher and REB.
- An REB gains much of its trustworthiness based on its construction. It includes persons who are trained in the technical field, the law and ethics. It also includes a member from the public who is independent of the institution. This composition typically translates into a five-person board, with two experts in the field, a person trained in the law, a person trained in ethics, and the community member.
- Another element of the commonized process is training. Every member of the REB must undergo trained required by the TCPS.
- A review conducted by an REB is an assessment of whether a project is ethical. In essence, a review is ex ante oversight of the researcher before he or she begins or at points where the research maybe changed.
- The REB process is review of the research but is not oversight of the REB.
- The researcher has a role in informing the review but does not participate in the review.
- The REB process is not an oversight of an institution but rather is review of research by researchers in an organization in a trustworthy manner based on a commonized set of rules.
- In sum, the REB process is not an oversight process for institutions, but rather a highly commonized framework and set of requirements for when reviews of research are required, how they will be conducted, the makeup of the body that conducts the reviews, and governance of that body within the institution. Trustworthiness comes from the commonized process and repercussions if institutions deviate from the rules.

Elements necessary to make business assessments similarly trustworthy
- To enhance the trustworthiness of business assessments of processing beyond individuals' normal understanding, similar to the trustworthiness associated with REBs,

a commonized framework for the environment in which assessments are conducted and a commonized framework for the assessment criteria might be established.

- The 2016 – 2017 Assessment Project created the Canadian Assessment Framework based on five core values that go beyond fair information values.
- The best practices for the environment in which assessments would take place was not within the scope of the Assessment Project. The participating organizations all have policies for how and when they conduct assessments, but they are different from organization to organization.
- Structural criteria for commonized better practices might include:
  o Direction on when assessments should be escalated to be more rigorous based on:
    ▪ The newness of the processing to the company;
    ▪ The data elements associated with the processing;
    ▪ How well understood the processing would be to stakeholders;
    ▪ The risks created for stakeholders.
  o The types of persons who should be part of the assessment.
    ▪ Experts (two as in REBs) in topics associated with the processing;
    ▪ A lawyer;
    ▪ A person focused on fair processing including ethical data use;
  o Direction on when outside expertise should be brought in as an advisor to the assessment process.
    ▪ That outside expertise could be a consultant or outside counsel.
  o Direction on when the voice of external stakeholders must be part of the assessment process, and how that outside voice might be added. That outside voice might be:
    ▪ A consumer or privacy advocacy community member, or
    ▪ Consumer focus groups.
  o Direction on the training necessary for those that take part in the assessment process.
  o Direction on independence from the proponent for the processing taking place (similar to the researcher only informing reviews and not participating in the decisions made by the REB),
  o Direction on the authority established for the assessment process.

Institutionalization within the current legal environment
- Common direction for both assessment criteria and the structure under which assessments might take place could be established either by a group of organizations jointly adopting a complete framework or as guidance for good practice by regulatory agencies.
- If established by a group of organizations, those organizations should make the framework public and should announce they are following the framework. Those organizations might enhance trust by publishing metrics on the elevated assessments conducted

- If established as guidance by regulatory agencies, the guidance should be developed with input from all stakeholders and published by the regulatory agencies. Organizations adopting the guidance should do so publicly, and trust might be enhanced by release of metrics about the number of assessments conducted.
- The common practices could become the basis for codes of conduct where an accountability agent conducts reviews of the assessment processes conducted at participating businesses to assure they are conducted according to the guidance and with integrity and competence.

Continued points of contention
- Some non-business privacy advocates believe that external assessment agencies could be created that would conduct escalated assessments that would have true independence. There are private Independent Review Boards (IRBs) in some jurisdictions, and some universities are considering the creation of this service. Furthermore, a number of companies in the United States that conduct scientific research have created their own IRBs.
- A number of regulators already review PIAs for public sector entities. The IAF has concerns that such a service would not be scalable if provided to the private sector.
- The new European Union General Data Protection Regulation (GDPR) requires some data protection impact assessments be reviewed by regulatory agencies if there is residual risk. However, there are concerns in the EU about scalability.
- The role of the community representative raises scalability issues too. The volume of reviews conducted by REBs is far less than those that would be conducted by their counterpart in business, ethical data review boards (EDRBs). The IAF is concerned that none of the proposals to address the scalability issue are feasible due to the magnitude involved.

Principles for internal EDRBs
- Analogous to the REB commonized process but appropriate for internal EDRBs, principles for internal EDRBs could be:
    - Accountability and Proportionality
        - The Canadian Assessment Framework is an example assessment
        - An organization structure under which assessment will take place, like the TCPS, needs to be developed
    - Stakeholder Interests
        - Assessments must reflect the full range of internal and external interests
    - Independence
        - Review of assessment must be independent of assessment process
    - Voice of the community
        - Focus groups
        - External experts
    - Transparency and Oversight
        - Structure and charter of the EDRB should be made public

- Organization should be ready to demonstrate its governance process
- These principles most likely are more appropriate for larger organizations.

Oversight Project Background

2016 - 2017 Assessment Grant

In 2016 the IAF received the Assessment Grant, supplemented by funding from twenty Canadian organizations or Canadian offices of multinational companies and in-kind services from Osler Hoskin & Harcourt LLP, to create for the Canadian context an assessment process (Canadian Assessment Process) to determine whether big data undertakings are legal, fair and just (Canadian Assessment Project). Three meetings were conducted with business to understand the application of federal and provincial private sector law, the balance between the role of the two pillars of Canadian law, consent and accountability, and how to augment PIAs already being conducted by leadership organizations in Canada in order to additionally assess for the ethical proxy of legal, fair and just. Based on those meetings, the IAF created the Canadian Assessment Framework that included a discussion of the linkage between an enhanced assessment and accountability. The IAF conducted a multi-stakeholder session to evaluate the Canadian Assessment Framework. The Federal Commissioners office, and authorities from British Columbia, Alberta, Ontario, Quebec and Newfoundland, submitted comments and/or participated in the multi-stakeholder session. Academics, advocates and business also participated in the multi-stakeholder session.

Unanimously, non-business stakeholders thought oversight of big data assessments was an issue that needed exploring. The non-business stakeholders were concerned that assessments conducted solely by business would not be trustworthy and that assessments done solely within a business would not be ethical. However, many of the businesses stakeholders were concerned that oversight would be costly, not scalable, create new liability, and impact confidentiality.

The IAF's report for the OPC raised the trustworthiness questions and suggested external oversight over internal assessments by something similar to REBs might be feasible. The question of trustworthiness of accountability processes in general and assessments specifically, are not new. The IAF was incorporated to explore accountability as a foundational element in privacy management and enforcement.[1] The Assessment Project is a continuation of basic accountability work that began formally in 2009 with the "Data Protection Accountability: The Essential Elements"[2], the foundation for the Canadian guidelines on "Getting Accountability Right with a Privacy Management Program"[3]. The underpinning for

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[1] The IAF is the incorporation of the Global Accountability Dialogue, an independent project founded in 2009 and housed at the Centre for Information Policy Leadership.

[2] The Centre for Information Policy Leadership (2009), "Data Protection Accountability: The Essential Elements", http://www.huntonfiles.com/files/webupload/CIPL_Galway_Accountability_Paper.pdf.

[3] The Office of the Privacy Commissioner of Canada (OPC), and the Offices of the Information and Privacy Commissioners (OIPCs) of Alberta and British Columbia,

Oversight Project occurred during IAF's first year when the role of accountability agents was discussed in a multi-stakeholder dialogue hosted by the UK Information Commissioner. That dialogue recommended the IAF conduct research on the attributes of trustworthy accountability agents that would, in turn, lend trustworthiness to assessments.

The question of trustworthiness continued to arise as IAF's work on big data progressed. The IAF began the Big Data Ethics Initiative in late 2014. IAF was charged with thinking about the broader issue of accountable big data processing and brought together numerous thought leaders, including former data protection commissioners, to discuss the issues related to trustworthy big data processing. Based on that discourse, IAF published A Unified Ethical Frame for Big Data Analysis in October 2014 (Unified Ethical Frame). The Unified Ethical Frame is based on key values and the need for an assessment framework, a set of key questions to be asked and answered to illuminate significant issues both for industry and for those providing oversight to assess big data projects.

In 2015, the data protection authorities in Spain and Italy hosted an IAF dialogue on how enforcement might have the authority to provide oversight to big data assessment projects. That work led to a paper that found the elements of an assessment process can be commonized in alignment with the Essential Elements of Accountability (Enforcement Paper). Those elements include:

- Internal policy that mandates assessments and their integration in internal governance
- Assessment tool that contains the elements of the assessment framework
- Decisions, mitigations and evidence used to make those conclusions
- Internal oversight of the big data process
- Standing ready to demonstrate the process

The research also established that a commmonized structure may be recognized in different manners. In some countries, it could be recognized as a code of conduct, and in other countries it could be recognized as a code of practice. In some countries that code of conduct may be enforced directly as a recognized code or as an extension of legal requirements (this view has been supported by the GDPR. There are other countries where authorities are ombudsmen and where a commonized process may be recognized as a code of practice that is encouraged rather than enforced (the research classified Canada as being part of this group).

The 2016 - 2017 Assessment Project, along with discussions in Europe, convinced IAF that the time was ripe for an oversight discussion specifically focused on making assessment processes trustworthy.[4]

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https://www.priv.gc.ca/media/2102/gl_acc_201204_e.pdf

[4] The enactment of the GDPR has also contributed to that clarity.

The Oversight Project

2017 – 2018 Oversight Grant

The outstanding question from the assessment project was what organizations conducting assessments could do to instill trust in the assessments they conducted. In conversation with privacy enforcement agencies, three approaches were discussed:

- a commonized process for assessments within a framework similar to REBs,
- codes of conduct administered by a third-party accountability agent, and
- assessment processes that were directly overseen by regulators.

The IAF received the Oversight Grant from the OPC to look at option one, a commonized oversight process for assessments that captures the attributes of REBs. As part of the Oversight Grant, the IAF has conducted research on how REBs operate, discussed commonized processes with a group of businesses, and conducted a multi-stakeholder session on February 15, 2018 with regulators, academics, advocates and business.

The IAF began the research with the key stakeholder concerns that a business will place its interests ahead of those of individual and societal stakeholders, or that some organizations conducting assessments will not have the skill sets to assure competent assessments. There was also a stakeholder concern that big data processes would not be visible to individuals in a manner that would lead to consumer complaints that would trigger investigations. Many business stakeholders understand the trust issue, while others are not even comfortable with the concept of assessments. Some business stakeholders would value an oversight process that might enhance trust. However, almost all business stakeholders have strong concerns about oversight processes. They are concerned that oversight will be costly, will not be scalable, will create legal liability that does not currently exist, and will impact confidentiality. Furthermore, there is great concern that oversight processes looking at data will have some of the insensitivity to immediacy that bothers many members and users of REBs.

An evaluation of three different models, with an emphasis on an REB model, including a clear documentation of all stakeholder concerns, has furthered the policy discussions on the implementation of trust enhancing protections that might come from effective oversight. The Enforcement Paper identified the elements necessary for an assessment framework to fit into a code of conduct or a code of practice that might be overseen by an oversight process either on demand or as part of a regulatory requirement and is the basis for the Oversight Project. The overall goal of the Oversight Project is to form a consensus view on oversight models for assessment frameworks that will be both trustworthy and scalable, and the objectives of the Oversight Project are to obtain a detailed understanding of an REB model that might be adopted via laws, implementing rules or industry best practices to enhance trust that data is being used in a legal, fair and just manner and to report these findings. In conducting the research in Canada, IAF is considering the other two models but is not exploring them in depth.

OPC Consent Report

During 2016 – 2017, the OPC conducted a consultation on consent. That consultation included an initial discussion paper, written submissions in response to the paper, five stakeholder roundtables, focus groups held in four cities, and peer review of the initial discussion paper. A Report on Consent was published as part of the OPC's 2017 report to Parliament (Consent Report).

Big data is truly a proxy for the analytic uses of personal data that go beyond the individual's imagination. Big data makes use of data not typically created or collected for big data analytic purposes but rather for other purposes such as risk assessment, fulfillment, marketing, and other purposes that are readily recognizable and understood by individuals. In Canada, individuals provide consent for those purposes. Sometimes, broad data-driven research is contained in the purpose specification notice. At other times, consent for big data research may be implied. Section 7(2)(c) of the Personal Information Protection and Electronic Documents Act (PIPEDA) also contains an exception to consent when personal data is used for research. However, the stretch between the readily apparent purposes and big data uses are beginning to concern policy strategists and may create legal and reputational risk for data controllers.

The Consent Report concludes that consent and accountability still should be the primary means for governing data use. The Consent Report considered the notion of independent ethics review boards, borrowed from the academic research context, and observed that stakeholders generally felt it does not transpose well in the commercial world. Nonetheless the OPC believed that incorporating an ethics lens into privacy protection is an important and worthwhile discussion but acknowledged that the incorporation of ethics into privacy law, whether in the form of consumer ethics boards or otherwise, is not yet developed enough to be practical in the short term. The OPC decided to continue to monitor developments on this front.[5]

Also, the concept of socially beneficial activities was articulated in the Consent Report. In proposing that Parliament consider amending PIPEDA to introduce new exceptions to consent, the OPC stated that such exceptions should be limited to circumstances where the societal benefits clearly outweigh the privacy incursions and where several prior conditions must be met before information can be used for such purposes.

The OPC recommended that Parliament consider the circumstances where such exceptions might be warranted from a broader societal perspective and identified examples of situations where in its view exceptions might be warranted: search engines indexing web sites and presenting search results to Internet users where appropriate; geolocation mapping services that society has become increasingly reliant upon; or certain data processes, such as big data analytics, Internet of Things, artificial intelligence or robotics applications where commercial and societal interests align.

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[5] Consent Report at 17.

As for prescribed prior conditions, the OPC stated these could include an organization having to demonstrate, on request, that:

- It is necessary to use personal information;
- It is impracticable to obtain consent;
- Pseudonymized data will be used to the extent possible;
- Societal benefits clearly outweigh any privacy incursions;
- A PIA was conducted in advance;
- The organization notified the OPC in advance;
- The organization has issued a public notice describing its practices; and
- Individuals retain the right to object.

The OPC also is of the view that a new consent exception would necessarily have to be contingent on stronger enforcement powers that would authorize privacy regulators, where warranted, to assess whether the use of personal information was indeed for broader societal purposes and met the prescribed legal conditions. This would be accomplished with proactive enforcement and not through prior-authorization, thereby moving away from the ombudsman system.[6]

Multi-stakeholder participants commented that there is a question of timing with respect to socially beneficial activities. Big data can be hypothetical and therefore rest on future speculation, so the question is beneficial when.

REBs

An REB is a group of individuals responsible for reviewing a clinical research study to make sure that the human research participant's rights and welfare are protected. In Canada, REBs are governed by the TCPS issued in 2014. TCPS covers what type of research should be subject to an REB, how REBs are constructed, and the skills necessary for competence.

Respect for human dignity is an underlying value of the TCPS. Respect for human dignity is expressed through three core principles: respect for persons, concern for welfare and justice.[7]

While the Tri-Council Guidance uses the term review, the product of an REB is an assessment. Typically, it is an escalated assessment where issues and risks are considered. It is a commonized process that adheres to common criteria set forth in the TCPS. While REBs are review of research projects proposed by researchers affiliated with the institution, they are not oversight of the REB itself. The commonized process creates the basis for researcher oversight if issues arise while the research is being conducted.

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[6] Consent Report at 15-16.
[7] TCPS at 2, 67

REBs have independence within the institution and independence from the individuals conducting the research but are not independent of the institution. It is appropriate for researchers to provide information to the REB but not appropriate for them to participate in the REB decision-making process. Multi-centre review processes have been established to coordinate reviews at different research sites, but there are instances where two different REBs have reached different conclusions.

Participants in the multi-stakeholder session commented that some stakeholders in the Canadian research community have been trying to put in place a government sanctioned accreditation process that oversees the review process. It is recognized that this exists in the U.S. but is lacking in Canada.

TCPS Chapter 6

Chapter 6 of the TCPS, Governance of Research Ethics Review, covers the establishment, composition and operation of REBs. Each institution must establish or appoint an REB to review the ethical acceptability of all research involving humans conducted by their faculty, staff or students (Members). Institutions may have more than one REB depending on the range, volume and type of research for which the institution is responsible. For instance, in larger institutions, biomedical research and social science research typically will be reviewed by different REBs comprised of different Members with different expertise. If Members of the institution make reference to their affiliation to the institution or use any of its resources, they should submit their research proposal to their institutional REB for research ethics review. Any research conducted under the auspices of an institution funded by a federal funding agency, or other sponsor that has adopted TCPS, must be submitted for REB review. The highest body within the institution establishes the REBs, grants the REB the mandate to review the ethical acceptability of research involving humans (including approving, rejecting, proposing modification to, or terminating any proposed or ongoing research), defines the reporting relationship with the REBs, and provides REBs with necessary and sufficient financial and administrative resources. REBs are independent in their decision-making but are accountable to the highest body that established them for the process of research ethics review.[8]

REBs should consist of at least five Members. At least two Members should have expertise in the relevant research disciplines, fields and methodologies; at least one Member should be knowledgeable in ethics; at least one Members should be knowledgeable in the relevant law, and at least one Member should have no affiliation with the institution. To ensure the independence of REB decision-making, institutional senior administrators should not serve on the REB. "The mere presence of a non-voting institutional senior administrator at REB meetings may be a source of real, potential or perceived conflict of interest . . . ."[9] There also should be substitute Members with the appropriate knowledge, expertise and training so REBs can continue to function when regular Members are unable to attend due to unforeseen

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[8] Id. at 67-69
[9] Id. at 70-71

eventualities. Members should be provided necessary training to effectively review the ethical issues raised by research proposals that fall within the ambit of their REB. REBs should have a chair and should have regular in-person meetings.[10]

Researchers should submit their research proposals for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, access to data, or collection of human biological materials. In keeping with a proportionate approach to research ethics review, the level of risk determines the level of review necessary: "the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review)." In delegated REB review of minimal risk research, the REB delegates research ethics review to an individual or individuals. Researchers may participate in discussions about their proposals and may be invited to provide further information about their proposals, but they may not be present when the REB is making its decision. When an REB is considering a negative decision, the researcher should be provided with all the reasons for doing so and be given an opportunity to reply before a final decision is made. At a minimum, continuing research ethics review should consist of an annual status report (for multi-year research projects) and an end-of-study report (for projects lasting less than one year). Any unanticipated issues or events that may increase the level of risk to human research participants or may have other ethical implications should be reported by the researcher to the REB.[11]

TCPS Chapter 7

Chapter 7 of the TCPS, Conflicts of Interest, addresses conflicts of interests from the perspective of the institution, Members and researchers. Because the question of the role of the outsider, particularly with respect to independence and compensation, is such a difficult one, participants in the multi-stakeholder session suggested that Chapter 7 of the TCPS provided insight as well.

Interests include, but are not limited to, business, commercial or financial interests pertaining to the institution and/or the individual, their family members, friends, or their former, current or prospective professional associates. It is preferable to avoid or prevent being in a position of conflict of interest, if possible, but when it is not possible to avoid a conflict of interest, then the conflict should be disclosed and steps should be taken to minimize or manage the conflict. If the conflict cannot be managed, then the institution, the researcher or the Member may need to abandon one of the interests in conflict.[12]

Reasonable compensation by institutions for work done by Members is appropriate. However, in some instances, individual Members may have a conflict of interest in accepting undue or

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[10] Id at 72-75
[11] Id. at 76-81
[12] Id. at 89

excessive honoraria for their participation in the REB. Institutions should define appropriate levels of compensation.[13]

As part of a research project submitted for REB review, researchers should disclose all kinds and amounts of payment (financial and in-kind) to the researchers by sponsors, commercial interests, and consultative or other relationships, as well as any other relevant information that may affect the project (e.g. donation by a research sponsor). The REB should examine budgets to ascertain whether there are inappropriate payments to be made or other unexplained expenses that may raise questions about conflict of interest.[14]

Canadian Assessment Process

The Canadian Assessment Framework may be used as big data activities reach key milestones or decision points. Some level of assessment may be appropriate at each phase of a big data activity. Big data analytics may include phases when the activity is first conceived, then approved for programming, put into operation and eventually reviewed. Questions need not be repeated in later phases if underlying conditions have not changed. If there have been changes to the activity that impact answers, then the questions may need to be repeated. If questions between the two assessments are duplicated, then they may not need to be repeated, and organizations may need to determine where in their processes it makes sense for the questions to be asked. Benefits and risks, and their likelihood of materializing, may be assessed based on an organization's approach to risk. As new data analysis and new applications of insights can change over time, the process of assessing benefits and risks may need to be repeated. Regardless of when the assessment is conducted, the results of each assessment may be presented to decision makers for a determination on whether to proceed with an activity.

Big data analytics may not be equally impactful on the individuals to whom the data pertains. Big data analytics usually can be separated into two phases: "thinking with data" and "acting with data". Generally, "thinking with data" is where new insights, which go beyond experience and intuition and come instead from correlations among data sets, are discovered. "Acting with data," generally, is where these insights are put into effect and where individuals may be affected as these insights are employed in an individually unique manner. The obligations of legal, fair and just apply to both the "thinking" and "acting" with data phases. While the "acting with data" phase often is individually impactful, the "thinking with data" phase may not be as individually impactful if aggregate data is used (the risks related to false insights usually are the primary concern in the "thinking with data" phase). If actions are taken on the "thinking with data," then the actions are "acting with data."

The IAF work has been clear that organizations conducting comprehensive assessments should be transparent about the processes they conduct and stand ready to demonstrate processes and assessments to oversight agencies that have the authority to establish that comprehensive

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[13] Id. at 94
[14] Id at 95-96

assessments were conducted with integrity and competence. A commonized set of excellent practices facilitates both transparency (to everyone) and oversight by authorities with authority. Participants in the multi-stakeholder session added that oversight also can be achieved by actions under the Canadian Competition Act[15] and that the commonized process should be recognizable, trustworthy and consistently replicable.

Escalated Assessments and Oversight

A key question raised in this research was whether the issue is escalated assessments or oversight of assessments. Websters Dictionary defines assessment as: "The action or instance of making a judgment about something." As applied, the Canadian Assessment Process would make a judgment that a processing is legal, fair and just based on the five values defined in the Canadian Assessment Framework. Websters Dictionary defines oversight as: "Watchful and responsible care." The Google Online Dictionary defines oversight as: "The action of overseeing something." The REB process is an escalated assessment process, where the assessment is conducted by a party that is independent of the research to be conducted, but it is given the qualities of being an oversight process because it is (a) conducted by a group independent of the researcher, (b) based on an established set of rules and procedures. So, the REB process shares the attributes of both assessments and oversight.

Almost all data protection regimes encourage or require assessment processes that include a triage process that first determines if there are issues that require further review (based historically on law, regulation, and publicly stated policies), and if there are issues a review that is proportional to the risks to stakeholders.   For example, new processing that is the same or roughly similar to processing that already has taken place requires either no assessment or more limited assessment. Processing that is completely new or raises traditional privacy issues (e.g. data is being used in a manner that is crystal clear from privacy notices and context) requires a PIA. Processing that goes beyond the common understanding of individuals creates risks that must be balanced against benefits or is highly complex requires a comprehensive assessment that establishes that the processing is legal, fair and just (not inappropriately discriminatory). The Canadian Assessment Framework contains such a comprehensive assessment. What the Canadian Assessment Framework does not contain is the commonized rules and procedures that would create the mechanism for oversight contained in the REB process. So, while the Canadian Assessment framework is an oversight process over the processing, it is not an oversight of the process that is essential to the trustworthiness of REBs.

Ethical Review Boards

The issue of how to add oversight to complex processings has been explored in the U.S. The Center for Law, Ethics and Applied Research (CLEAR) at Indiana University has conducted research on how IRB (the U.S. equivalent to REB) processes developed for human subject research might be updated for less intrusive data driven research. The CLEAR project suggests

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[15] R.S.C., 1985, c. C-34

ethical review boards (ERBs) would be part of an overarching triage process so that projects receive the appropriate level of review and the most sensitive projects are reviewed with appropriate independence and subject matter expertise.   The CLEAR project takes the concepts relating to IRBs and applies them to business research that is purely data driven and that does not require IRB review.

The ERB process is built on the premise that Universities are fundamentally different from businesses. ERBs are intended to evaluate data driven processes that do not fit into the traditional IRB structure. A number of U.S. businesses are establishing assessment processes that include the IRB-type of enhanced review. However, the concept of the independent/community member has raised issues of scalability, protection of trade secrets and the nature of true independence. The number of assessments in a business is much greater than in a university setting, secrecy is a significant issue for innovative organizations who are concerned that nondisclosure agreements are not dependable, and volunteer participation by the outsider is unfair for a profit-making organization but compensation makes the outsider a different member.

The U.S. ERB concept still lacks a commonized set of processes and procedures that has been essential for trust in REBs.

Independence of Business Processes

Participants in the multi-stakeholder session suggested that independent bodies might be created that provided the service of the community member for Ethical Data Review Boards ("EDRB"). EDRB is the term the IAF used in its proposal to the OPC and is the term that will be used in the remainder of the Oversight Project Report. For example, under the Asia Pacific Economic Cooperation Privacy Framework, accountability agents are certified and overseen by regulators (e.g. U.S. Federal Trade Commission).   However, the accountability agents do not participate in business activities. Instead, like a regulator, accountability agents provide an external oversight process that is fundamentally different from the function of an REB.

Stakeholders were also concerned about the authority of the escalated assessment process. They suggested that the power of an EDRB needs to be clear. There was confusion about whether an EDRB provides an advisory opinion or whether it has veto power. If the assessment process in a business refuses to approve a project, there was concern about whether the processing advocates could appeal to the chief executive officer.

The situation differs from business to business. However, business stakeholders suggested that in almost all cases if the review process raises troubling issues approval does not take place without changes that mitigate the concerns.

Regulator participants do have oversight responsibility over public sector institutions. They said that the threshold for processing beyond individuals' expectations is the processing is "necessary," while in the private sector the threshold is "reasonable".

Key Concepts Moving Forward in Canada

TCPS creates a commonized process[16] for assessing research activities involving humans to assure that they are ethical. The TCPS criteria create a level of consistency that is trusted: the researcher can inform the process but cannot participate in the decision-making process, the review is conducted within the confines of the institution, the requirement for a community member creates a check, and the commonized process creates the consistency that facilitates external oversight if necessary.

The Assessment Project created the Canadian Assessment Framework, a common framework for assessments for the private sector. However, the Assessment Project did not create a commonized set of protocols for the structure under which an assessment might take place. Each organization was left with complete freedom to determine which body within the organization would conduct an assessment and who might participate in such an assessment. Furthermore, the Assessment Project did not establish the authority for oversight of the assessment process.

The IAF's 2015 research on assessment enforcement discussed the creation of codes of practice and codes of conduct related to assessments. Sometimes when a code of conduct is referenced, what really is meant is a code of practice of best practices. Despite the difference in terminology, these different terms are used to achieve the same result – establishment and encouragement of industry best practices as it relates to maintaining comprehensive programs. For the purposes of this research, the term "code of good practice" will be used. However, the TCPS criteria are consistent with all three of these oversight models: codes of good practice, codes of conduct, and assessment processes directly overseen by regulators.

Codes of good practice may be established through regulator encouragement or ad hoc industry action. The Enforcement Paper sets forth the elements of a big data code of good practice that are consistent with the TCPS criteria:

- Internal policy that mandates comprehensive assessments and their integration in internal governance
- Assessment tool that contains the elements of the assessment framework
- Decisions, mitigations and evidence used to make those conclusions
- Internal oversight over big data processes
- Standing ready to demonstrate the process

While developed for big data activities, the Canadian Assessment Framework may be used to assess any activities within an organization where data is collected, used and disclosed in a manner that may not have been anticipated by the individuals to whom the data pertains. The

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[16] One participant in the multi-stakeholder session commented that "commonized process" sounded like a "process standard" (e.g. ISO9000 or ISO14000) and suggested that the Canadian Standards Association should resume the work it started some years ago.

Canadian Assessment Framework itself contains at least four of the five elements of a big data code of good practice:

- When implemented by an organization, the Canadian Assessment Framework is the manifestation of an internal policy mandating a comprehensive assessment, the first element.
- The Canadian Assessment Framework created a comprehensive assessment tool that satisfies the second element of a big data code of good practice.
- Utilization of the comprehensive assessment tool satisfies the third element (decisions, mitigations and evidence) and the fifth element (demonstration).
- The fourth element, internal governance and oversight, which can evolve from existing good practices in organizations, may be accomplished by a mixture of governance structures (e.g. the privacy organization combined with internal audit).

If the trust of the REB process is desired for private sector assessments, then something similar to the TCPS would be desirable. That guidance might be created by a private sector consortium or could be created by Canadian enforcement agencies as better practice guidance. It would have to address the key issues related to the environment under which assessments are conducted:

- What circumstances would require an escalated assessment;
- The makeup of the assessment board;
- Independence from the corporate group wanting to process data;
- Authority within the organization;
- Documentation of proceedings; and
- External expert participation.

Outstanding Issues

Community Representative

The manner in which the equivalent of the community member might serve on an EDRB was not settled at the multi-stakeholder session. Many from the advocacy community believed the role was crucial, while many from the business community were concerned about scalability and confidentiality. The scalability issue revolves around the volume of meetings at an EDRB versus the volume at an REB. REBs meet on a regular schedule, often monthly, while business reviews are conducted more often. When a committee meets on a monthly basis, the burden on the external volunteer is manageable. Query whether it is fair for a community volunteer to serve on an EDRB without compensation, and if they receive fair compensation whether they become another internal stakeholder.

It was suggested by business that they often reach out for external opinions. They often use focus groups to sense public sensitivities. However, this is at the organization's discretion and not based on an accepted set of external guidance.

For trust purposes, a resolution of the community representative issue is necessary.

Harms and Benefits

Harms and benefits are a key issue in assessments. Benefit is one of the key values in the Canadian Assessment Framework. The benefits value requires organizations to list the stakeholders, the benefits they may receive, and the risks and potential harms to each stakeholder associated with the processing. While it is a risk assessment, the only way to weigh risks is in the context of benefits, and therefore, an assessment needs to consider benefits as well as risks.

Not all participants in the oversight session agreed with business assessing benefits. Some participants thought the assessment should be about impact and intrusiveness (proportionality) rather than about risks and benefits. Under either approach, the organization has to articulate the probability of both the risks and benefits, both in terms of likelihood of the outcome and its impact.

Also, there are concerns that organizations will game the process. One participant pointed out that it is necessary to be careful not to double count benefits and risks (e.g. absence of benefit does not also constitute harm) and that there needs to be rigor in distinguishing between business and social benefits and cautioned with respect to "trickle down" economic benefits (i.e. the need to balance differing values). This participant thought that private businesses are not able to assess social benefit and harm because their time frames and horizons are too short (other participants disagreed because such inquiries are embedded in their processes) and if the intent is to create a safe harbor from liability, private businesses do not have legitimacy to evaluate social benefits.

IAF Findings and Insights

IAF has the following conclusions: (1) Having a standard to measure against for the nature of assessments, having a structure in which those assessments take place, and having transparency regarding the process and results are necessary to capture the virtues of REBs required to build trust. (2) No single solution will work for all organizations and situations. For example, an internal assessment framework with escalated assessments may work for the most complex and sensitive processing in large organizations based on commonized guidance but may not be scalable for smaller organizations that need to assess processing beyond expectations. For the most part, what IAF proposes will work for larger organizations. (3) The commonized process for large or more active organizations should be based upon principles for internal EDRBs.

- Key REB Concepts Applicable to Internal EDRBs

REBs are a commonized framework for assessing whether research projects involving humans are ethically acceptable.[17] Some key concepts learned from REBs that are applicable to data driven research in the business context include:

- Safeguards should be in place
- Research should respect human dignity through the full range of rights and interests
- An assessment framework should be based on and subject to a set of rules and procedures that are commonized in some fashion
- The EDRB should be composed of individuals who are knowledgeable about the ecosystem in which the processing is conducted, appropriate laws and regulations, and societal norms in play
- The processing advocate should inform the assessment process but should not participate in the decision-making process
- Members of the EDRB should receive training in their roles as EDRB members

- Code of Good Practice as the Basis for a Commonized Business Assessment Framework

The IAF believes a code of good practice for assessments would create the basis for commonized business assessment frameworks. Such a code of good practice might include

- Directions on when a comprehensive assessment should take place
- The roles and responsibilities of individuals who should be involved
- The training necessary to conduct a review
- When external expertise is necessary
- How independence from those with a direct stake in the processing should be maintained while still being able to conduct the decision-making process within the organization
- How the framework would be made public and the types of metrics to be published
- When assessments might be available

A voluntary code of good practice that has an REB-like commonized approach to comprehensive assessment for data driven private sector processing could capture the trustworthiness of REBs. In such a commonized process, comprehensive assessments would be part of the voluntary code of good practice framework that includes overarching policies that describe the necessary capabilities to define when comprehensive assessments are necessary and to determine whether comprehensive assessments are conducted in a competent manner. The voluntary code of good practice would also include an internal oversight process that measures whether comprehensive assessments are conducted with honesty and recognize the full range of stakeholder interests so that the interests of the organization are not placed in front of the interests of other stakeholders. The voluntary code of good practice should be publicly described, and metrics should be published. Comprehensive assessments should be

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[17] A participant in the multi-stakeholder session pointed out that in PHIPAA there are prescribed requirements for ethics boards and that ethics boards cannot fall below those standards.

documented to facilitate ex-post review by external bodies with appropriate levels of authority. A means for inserting a check similar to the community member of the REB would need to be resolved. A voluntary code of good practice could be encouraged by ombudsman regulators or by an ad hoc group of businesses.

A voluntary code of good practice is not the same as an independent external REB. One participant in the multi-stakeholder session suggested an external ethical review board is a necessity for trust. In response to concern that external ethical review boards are expensive and that if they are inexpensive they are not trustworthy, it was suggested that fewer external boards serving many businesses would be far less costly than many more separate internal boards (especially for small and medium-sized businesses that might not have the internal expertise to conduct a proper internal review). In this suggested system of external ethical review boards, expert members (possibly full-time to enhance their expertise), funded entirely by industry,[18] would receive, review and rule upon advanced analytics proposals on a confidential basis. There are discussions at one major University in the United States to create such an entity. In the Consent Report, the OPC concluded that the concept of an independent external REB is not yet developed enough to be practical in the short term and decided to continue to monitor developments on this front.[19]

The concept of an external ethical review board has merit for processing that might create great value but does so in a fashion that also raises risks that are not fully mitigated. An external ethical review board may also serve the needs of smaller organizations that do not have the size for a limited number of comprehensive assessments. IAF also believes issues of confidentiality raised by business as part of the multi-stakeholder session could be resolved. However, unlike clinical research, where the number of reviews is fairly limited by the cost of clinical research, the number of assessments that a modern observational ecosystem demands for there to be both innovation and protection is not scalable to meet market needs if all escalated business assessments required outside independent review.

With respect to the external community representative, one participant pointed to Chapter 7 of the TCPS as authority for providing reasonable compensation to the community representative as long as it is not undue or an excessive honorarium. The same participant also suggested that models for external community representation are found in labor arbitration (where a business contracts with an organization and does not know which staff member will participate) and the Center for Democracy and Technology (which acts as an outside advisor for its corporate funders). The IAF believes that a number of items may be linked together to equate to a sense of the what the community would consider appropriate. Where appropriate, an EDRB might conduct community sensing on a processing, similar to a focus group process, and where warranted, if external assessment services are created for the most sensitive research those

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[18] It was suggested that a n example of such an arrangement is the Canadian Commission for Complaints for Telecom-Television Services.
[19] Consent Report at 17.

services could include the appropriate background and expertise to bring the voice of the community.

- Principles for Internal EDRBs

Participants in the multi-stakeholder session thought the starting point for a commonized process for larger or more active organizations should be principles for internal EDRBs. Based on the research, IAF concludes the Principles for Internal EDRBs could be:

(1) **Accountability and Proportionality**   Assessment governance is an accountability process for organizations processing data that goes beyond the common understanding of the people to whom the data pertains. The governance system should link to external criteria for both the assessment process and the organizational structure under which it will take place. The scope of an assessment should be proportional to the complexity and the risks associated with the processing. The more complex the processing, the newer the approach, the greater the level and probability of the risk, the greater the rigor of the assessment should be. The escalation process might include external EDRBs when such entities are created.
   a. The Canadian Assessment Framework is an example of an external criteria for the assessment process.
   b. The organizational structural criteria, like the TCPS, still need to be developed. However, the structural criteria should specify the skills that need to be represented on an EDRB, the training necessary, the reporting required, and the EDRBs authority
(2) **Stakeholder Interests**   The full range of stakeholder interests are the dependent variable in an assessment governance system. Assessments must be conducted based on the full range of interests of the full range of stakeholders. The interests of external stakeholders must be at least co-equal to those of internal stakeholders.
(3) **Independence**   The EDRB must be independent of the internal advocates for the processing. Those advocates have a role in informing the assessment but not in making a decision. There may be interaction between the EDRB and the internal advocate in order to enhance benefits to external stakeholders and mitigate risks to individuals and society. The EDRB's authority must be established as part of the governance charter.
(4) **Voice of The Community**   The voice of the community should be represented on the EDRB. It may be represented by focus groups. Some organizations may recruit external experts that might represent the voice of reasonable members of the community. In any event, that voice should be documented as part of the assessment.
(5) **Transparency and Oversight**   The structure and charter of an EDRB should be made public and easily accessible. The external criteria that are used should be noted. Integrity and competence should be reviewed on a regular basis. An internal audit review is a better practice. The organization should stand ready to demonstrate its

assessment governance process and individual assessments to regulators with appropriate authority.

These Principles, and how they are linked to the operational detail in this Oversight Project Report, may be the appropriate starting point for continued research.