MULTI { SITE } ETHICS

REVIEW AND CLINICAL TRIALS IN CANADA

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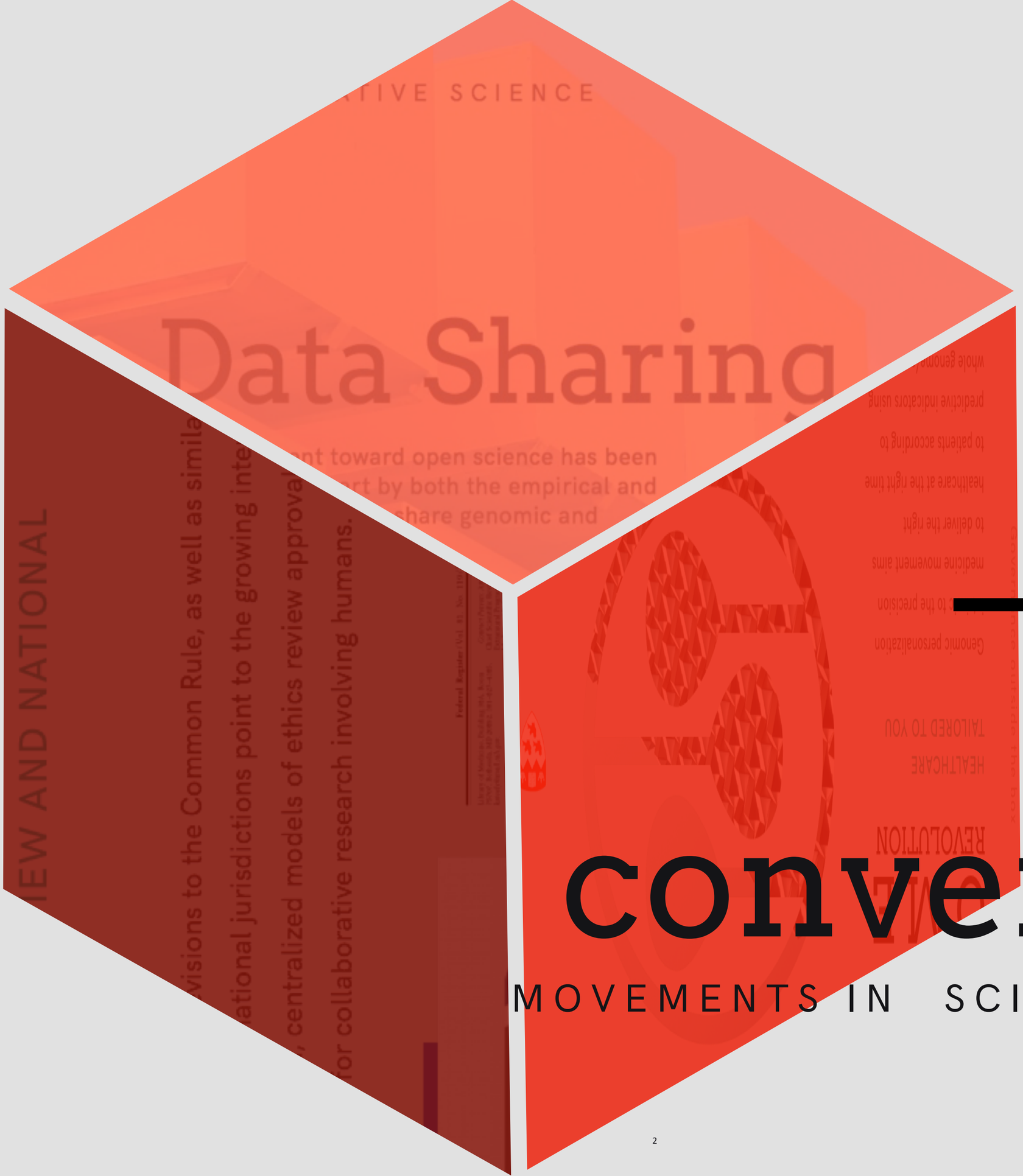

Data Sharing
converging
MOVEMENTS IN SCIENCE (POLICY)

COLLABORATIVE SCIENCE

Data Sharing

The movement toward open science has been driven in large part by both the empirical and ethical imperative to share genomic and health-related data

GEN OME REVOLUTION

Breaking the mold

HEALTHCARE TAILORED TO YOU

Genomic personalization intrinsic to the precision medicine movement aims to deliver the right healthcare at the right time to patients according to predictive indicators using whole genome/exome sequencing.

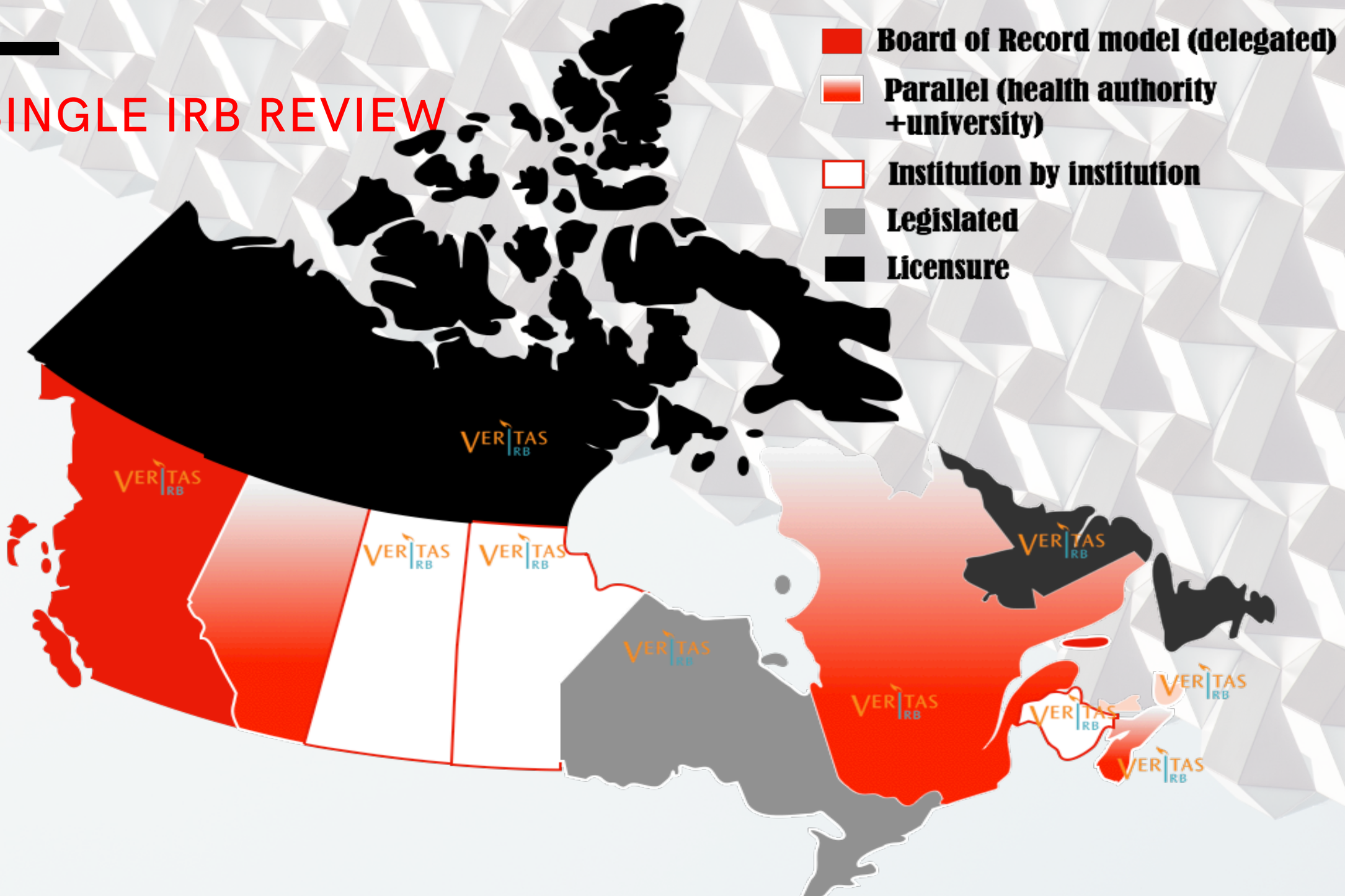
ETHICS REVIEW

#SINGLE

The single REB model, as an innovation in ethics governance, is purported to better respond to the contemporary realities and practices of collaborative, data-intensive research typified by stem cell research and genomics. Centralizing ethics review will limit—if not eliminate outright— redundancies and inefficiencies that at present plague this regulatory step on the bench-to-bedside continuum. It addresses a longstanding demand from stakeholders to reduce the procedural inefficiencies, redundancies and delays that have become synonymous with research ethics review under the extant system

The TCPS2 (2014) outlines three organizational models for research ethics review: independent, delegated and reciprocal. Until recently, the independent model was the most widely adopted in Canada. Several provincial reforms are transitioning from an independent to various delegated or reciprocal models of review.

SINGLE IRB REVIEW



Breaking the Mold

CANADIAN {CLINICAL} TRIALS

Coordinating Centre

Final recommendations on REB accreditation. The CCTCC (Canadian Clinical Trails Coordinating Centre) REB (Research Ethics Board) Accreditation Working Group (WG) was established in 2015 to identify strategies to improve efficiencies of ethics reviews and advance strategic issues like accreditation in regards to clinical trials. The establishment of the WG is consistent with Recommendation #4 of the Action Plant to Help Attract More Clinical Trials to Canada as well as Recommendation #3 of the Senate Report entitled "Canada's Clinical Trials Infrastructure: A prescription for Improved Access to New Medicines"

FINAL RECOMMENDATIONS

1. Establish a **registry of REBs** that review and approve clinical trials that could ultimately be expanded to encompass all REBs in Canada. 2. Actively pursue regulatory options for **standards equivalency for REBs** that review regulated clinical trials. 3. **Coordinate REB education** and training efforts, and conduct a needs assessment of REB education requirements.

4. **Investigate the feasibility** of various approaches to sharing REB reviews of multi-centre research (including a possible online system and a national data warehouse). 5. **Conduct a study of real and perceived barriers to the acceptance of other REB reviews** and publicly report on the findings and recommended solutions. 6. Establish a **national strategic leadership** forum.

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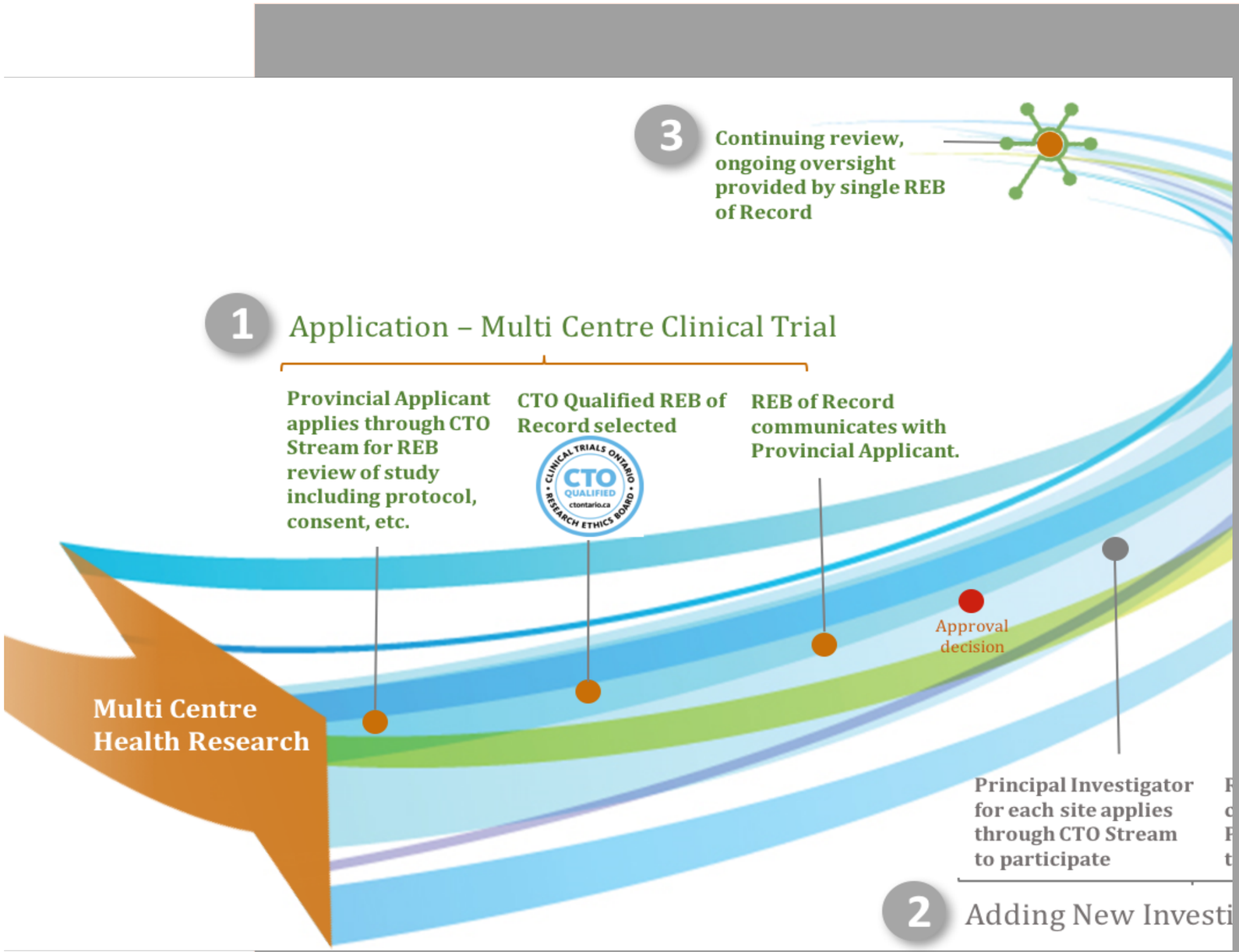

CLINICAL TRIALS

ONTARIO.

Clinical Trials Ontario (CTO) is an independent not-for-profit organization established with support from the Government of Ontario. Its mandate is to work collaboratively with the clinical trials community, the public and strategic partners to improve Ontario's clinical trials environment and attract clinical trial investment to the province, while supporting the highest ethical and quality standards. Its mission is to strengthen, promote and capitalize on Ontario's competitive advantages to conduct high-quality clinical trials.

single REB

fact or fantasy?

Operationalization & implementation

For its theoretical simplicity, sREB potentiates complex implementation challenges that, without practical guidance and infrastructural support, could negate any improvement in review quality or efficiency in terms of approval time and costs that motivated its adoption in the first place.

LIMITED EVIDENCE

Health services and policy research is lacking to demonstrate the superiority of a sIRB model.

INTER-INSTITUTIONAL RELATIONSHIPS

Practical guidance is lacking on how to navigate inter-institutional relationships

CULTURE OF (MIS)TRUST

Institutions anecdotally report (mis)trust in the procedures, competencies and approaches of other ethics boards.

limited

Empirical policy evidence

Health services and policy research is lacking to demonstrate the superiority of a sREB system over the status quo, despite extensive anecdotal and experiential evidence from researchers and institutions alike. .

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RESEARCH ETHICS REVIEW AND DATA SHARING

Kosseim *et al. Genome Biology* 2014, **15**:430
http://genomebiology.com/2014/15/8/430

Genome Biology

OPINION

Building a data sharing model for global genomic research

Patricia Kosseim[1], Edward S Dove[2], Carman Baggaley[1], Eric M Meslin[3,4], Fred H Cate[4,5], Jane Kaye[6], Jennifer R Harris[7] and Bartha M Knoppers[2*]

Abstract

Data sharing models designed to facilitate global business provide insights for improving transborder genomic data sharing. We argue that a flexible, externally endorsed, multilateral arrangement, combined with an objective third-party assurance mechanism, can effectively balance privacy with the need to share genomic data globally.

The opportunities presented by data sharing models

One of the great opportunities in the genomics era is exploring how human genes influence health, disease and biologic pathways, and how the knowledge gained can contribute to better health through both prevention and therapy. Researchers collaborating globally can gather sufficiently granular data to discover gene-environment-disease correlations for translational research and clinical application. Conducting scalable projects has been aided by the convergence of two key developments: vast improvements in, and access to, low-cost sequencing technology, and the increased power and sophistication of data analytics, driven by what has become termed 'Big Data' [1]. Big Data provides a new generation of data analytics technologies that extract value from large, complex datasets (including genome and health-related datasets) so as to enable rapid capture, discovery and analysis [2].

The analysis, integration and translation of these diverse types of health data present a real challenge for science and policy. Progress in our ability to impact human health is highly reliant on bringing genomic technologies to bear on Big Data in ways that maximize data use, while minimizing duplicative effort and costs. But leveraging such opportunities is contingent upon cultural and policy changes aimed at enhancing genomic data sharing across borders.

Data sharing
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While a cu
emerging, significant policy impediments to transborder data sharing remain [9]. Given the growing interest to combine individual-level genotype and phenotype data to understand better the determinants of health and disease, the more realistic starting assumption is that such data are, or might be, personal in nature. Genomic and clinical data sharing as a practice is challenged by regulatory systems originally developed to protect personal data within single jurisdictions [10]. These older data protection regimes are no longer attuned to the evolving paradigm of large-scale global health research, often resulting in inefficient data flow, significant costs and delays. For instance, in a recent literature review cataloguing barriers to sharing in biobanks, Colledge and colleagues remarked that 'the divergence of regulations on the … transfer … of tissues and data is repeatedly mentioned as an obstacle to international collaboration'

A flexible, externally endorsed, multilateral arrangement, combined with an objective third-party assurance mechanism can effectively balance privacy with the need to share genomic data globally.

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Ethics review for international data-intensive research*

Edward S. Dove[1,*], **David Townend**[2], **Eric M. Meslin**[3], **Martin Bobrow**[4,5], **Katherine Littler**[6], **Dianne Nicol**[7], **Jantina de Vries**[8], **Anne Junker**[9], **Chiara Garattini**[10], **Jasper Bovenberg**[11], **Mahsa Shabani**[12], **Emmanuelle Lévesque**[13], and **Bartha M. Knoppers**[13]

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In addition to moving toward common ethics review standards and procedural alignment, common conditions for exchanging data should be developed, which we believe would make RECs more inclined to mutual recognition of ethics review.

Historically, research ethics commit
regarding human experimentation i
to provide assurance as to their inte
aggregate data sets, possibly includi
individuals, may require different assessment. At the same time, growth in international data-sharing collaborations adds stress to a system already under fire for subjecting multisite research to replicate ethics reviews, which can inhibit research without improving the quality of human subjects' protections (1, 2).

"Top-down" national regulatory approaches exist for ethics review across multiple sites in domestic research projects [e.g., United States (3, 4), Canada (5), United Kingdom, (6), Australia (7)], but their applicability for data-intensive international research has not been considered. Stakeholders around the world have thus been developing "bottom-up" solutions. We scrutinize five such efforts involving multiple countries around the world, including resource-poor settings (table S1), to identify models that could inform a framework for mutual recognition of international ethics review (i.e., the acceptance by RECs of the outcome of each other's review).

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Mutual recognition

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The purpose of this Policy is to provide Essential Elements of ethics review recognition for **multi- jurisdictional research projects involving health-related data.** The two express goals of the Policy are to both foster recognition of extra-jurisdictional ethics reviews and improve the consistency thereof, as well as to promote efficient and responsible health-related data sharing for human health and wellbeing.

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Global Alliance for Genomics & Health

ETHICS REVIEW RECOGNITION POLICY

Version: 13 February 2017

Global Alliance for Genomics and Health: Ethics Review Recognition Policy

Preamble

The Global Alliance for Genomics and Health ("GA4GH") is an international, non-profit coalition of individuals and organizations working in healthcare, research, disease advocacy, life sciences, and information technologies dedicated to improving human health by maximizing the potential of genomic medicine through effective and responsible data sharing. Its mission is "to accelerate progress in human health by helping to establish a common framework of harmonized approaches to enable effective and responsible sharing of genomic and clinical data, and by

INTER INSTITUIONAL RELATIONSHIPS

PRACTICAL GUIDANCE AND MOUS

Practical guidance is lacking on how to navigate inter-institutional relationships

Breaking the mold

Cultures of (Mis)trust

Administrators report (anecdotally) mistrust in the procedures, competencies and approaches of other ethics boards.

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CHALLENGES

HARMONIZING THE HARMONIZED

Many provinces have reformed, or are in the process of reforming their research ethics review oversight model for multisite research within the provinces. Yet provincial action has not been met with corollary policy activity at the federal level. This may continue to pose inter-provincial challenges for multijurisdictional studies across provinces and internationally.

Blockchain inspired governance?

One of the most extraordinary outcomes of the digital revolution is that multi-stakeholder networks now govern important global resources

Tapscott 2014

Systems, Layers III, *Matthias Heidrich*

Conceptual virtues

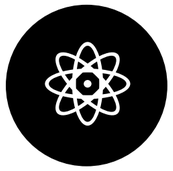
OF THE BLOCKCHAIN

Unfalsifiable documentation

Data that are stored on a permission ledger would be immutable proof of the terms of the study approval and the REC decisions recognized across all participating sites. This would enable REC transparency, accountability and empirical research on REC performance.

Smart contracts

An encrypted code that algorithmically executes permissions outlined in an agreement (e.g. consent form, study protocol, data sharing). Once verified, these contracts bind any changes in these agreements to the consent/approval of participating sites and participants, if applicable.



Direct connectivity

Affords investigators and patients direct access to all RECs, allowing for immediate appraisal on changes to study procedures and findings, including those that may alter the risk-benefit calculus of a study, among others. The end-to-end connectivity of the blockchain fosters a truly multi-stakeholder network that sees participants, researchers and governances bodies such as RECs as peers.

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