This paper was presented at the XXXVII ISPIM Innovation Conference, held in Granada, Spain on 07 June to 10 June 2026. ISBN 978-952-65771-2-8.

Reassessing Institutional Authorization: Innovating the Effectiveness for Human Research Protection

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Abstract: Canada's human research oversight operates within a fragmented regulatory and governance landscape, creating challenges for institutions responsible for ensuring compliant and safe research conduct. The Institutional Authorization (IA) model addresses this complexity by enabling institutions to better manage risk, improve operational efficiency, and foster a culture of quality and safety. This approach allows Research Ethics Boards (REBs) to focus on ethical feasibility and appropriateness, without extending their mandate to broader institutional responsibilities. In addition to supporting a single REB review model for multisite research, IA enables structured institutional oversight for non-research activities (e.g. data registries and quality improvement) where ethics review may not be required. Targeted implementation through a multi-year institutional pilot has resulted in measurable improvements in efficiency, timeliness, and oversight, leading to faster study activations while maintaining strong protection for research participants. Learnings will serve to establish a predictive model to better respond to delays in study activation.

Keywords: Research ethics; human research; research ethics board; research ethics committee; institutional review board; research ethics review committee; human research protection program; institutional authorization; regression analysis; factor analysis; predictive analysis.

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1 Introduction

Clinical research in Canada operates within a complex, fragmented regulatory environment (McDonald et al., 2011) involving multiple federal and provincial policies that extend beyond research ethics, making oversight difficult for large, decentralized research institutions (Alas et al., 2017; Lamontagne et al., 2021). Traditionally, Research Ethics Boards (REBs) have served as the primary gatekeepers for human research, tasked with ensuring ethical feasibility and appropriateness (Legand, 2010; Owen et al., 2009). Over time, however, REBs experienced mission or "ethics creep" (Robson and Maier, 2018), gradually assuming responsibilities beyond ethics such as coordinating institutional approvals, overseeing research integrity, and ensuring compliance with internal policies (Friesen et al., 2018; Nuttgens, 2021). These activities strained resources, delayed approvals, and duplicated effort for researchers.

These challenges were amplified in multisite research, where multiple local REB reviews often led to inconsistent decisions and prolonged timelines. This prompted the adoption of a "single REB review for multisite research" model, designating one Board of Record to conduct ethical review. While more efficient, this model reduced the ability of local REBs to coordinate site-specific, non-ethical oversight, highlighting the need for alternative institutional mechanisms (Alas et al., 2017; Diamond et al., 2019; Green et al., 2023; Hébert and Saginur, 2009; Klitzman et al., 2019; Lidz et al., 2018; Petrova and Barclay, 2019; Taylor et al., 2019).

In response, the University Health Network (UHN) introduced an Institutional Authorization (IA) model in 2011. The IA model separates ethical review from other institutional reviews by allowing the REB to focus solely on ethics while other compliance, regulatory, service provision, and impact assessment groups independently assess feasibility and risk in their respective domains (Desai et al., 2017). IA becomes the formal authorization required to begin human research, enabling institutions to suspend or terminate studies for non-ethical reasons without compromising REB independence. The model also supports single-REB multisite research by ensuring local non-ethical reviews still occur.

To operationalize IA at scale, UHN developed the Coordinated Approval Process for Clinical Research (CAPCR), a centralized, web-based system that streamlines submissions across the entire study lifecycle. CAPCR consolidates previously fragmented application forms into a single, dynamically generated submission tailored to study complexity and risk, routing it to the appropriate internal review groups. Since its introduction and subsequent expansion, CAPCR has become a "one-stop shop" for human research approvals at UHN, supporting thousands of studies annually and coordinating reviews from an expanding network of stakeholders.

Overall, the IA model and CAPCR system demonstrate a systems-based approach (Fontanesi et al., 2018) to managing the growing complexity of clinical research oversight, reducing duplication, mitigating institutional risk, supporting multisite research, and allowing REBs to refocus on their core ethical mandate within a large academic health research network.

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2 Planning and Implementing a System to Manage Institutional Authorization

Planning for UHN's Institutional Authorization (IA) policy began in 2007 and culminated in its formal release in June 2011, alongside the development of the CAPCR system. Existing institutional review and approval forms were consolidated into a single, streamlined application by eliminating duplicate questions and organizing content into logical sections.

The CAPCR system was developed collaboratively by the REB and major stakeholder groups such as Pharmacy, Imaging, Biosafety, Radiation Safety, Biobanks, Responsible Conduct of Research, and Contracts/Legal (Fontanesi et al., 2018; Trace and Kolstoe, 2018). CAPCR uses an initial "Study Profile" to determine which reviewers are required and dynamically builds the application based on the type and risk of the proposed research, with more complex studies triggering more review sections and reviewers.

Launched in 2012, the first version of CAPCR supported initial submissions only and ensured that all required reviews were completed before IA was granted, marking a significant cultural shift since REB approval alone was no longer sufficient to initiate human research. This change required extensive communication, education, and the establishment of a help desk to support both applicants and review groups.

In 2016, CAPCR Version 2 expanded the system to cover the full study lifecycle, including amendments, annual renewals, reportable events, and study closures, supported by dedicated education and support teams. Over time, the number of potential review groups grew from about 20 to more than 120, with typical studies triggering around 5 reviewers and complex clinical trials triggering approximately 11 reviewers.

3 Developing Metrics and Performance Indicators for the Institutional Authorization Model

CAPCR was intentionally designed not only as a submission and communication tool, but also as a data warehouse and reporting system to strengthen institutional oversight of human research at UHN. The system included built-in reporting capabilities allowing administrators, review departments, clinical research units and even study teams to analyze performance using both high-level metrics and detailed, granular data. Key data points were standardized across the institution and extended to external systems such as Clinical Trials Ontario (the Board of Record Process for multi-site research in Ontario, Canada) and the ClinicalTrials.gov registration database, enabling effective data linkage across platforms used internally and externally.

Over time, CAPCR data has provided insight into research volume, study lifecycles, and review workload. Submissions increased from just over 520 new studies in 2012 to an average of more than 1,100 studies annually. The 2016 CAPCR Version 2 upgrade expanded data capture across the full study lifecycle, enabling reporting at the study, submission, and review-decision levels. With over 1,400 dynamically generated questions, CAPCR supports sophisticated analysis of study characteristics while ensuring forms remain proportional to study risk and complexity. Institutional Authorization (IA) is applied not only at the study level but also across ongoing submissions such as amendments

and renewals, meaning IA status can be gained or lost based on continued compliance (e.g., REB expiry). This approach allows more accurate measurement of institutional workload by capturing review activity per submission rather than per study. It also provides a centralized resource hub where all study-related submissions are electronically managed and maintained, supporting ease of use and transparency across the research lifecycle.

During the COVID-19 pandemic, CAPCR's reporting capacity enabled UHN to rapidly develop real-time dashboards to track COVID-19 research, prioritize approvals, and monitor the broader impact of the pandemic on research activity. Data showed shifts toward COVID-related studies, overall declines in submissions during research ramp-downs, and fluctuations aligned with key pandemic waves. This demonstrated the value of having a well-established and robust data infrastructure in place before a crisis, rather than attempting to build one in response to it.

CAPCR metrics are also used for continuous system and process improvement. Key performance indicators (KPIs) capture indicators such as "approval not required" decisions and "median time to review decision", help identify over-triggering or unnecessary triggering of reviewers, inefficiencies in question wording, and process bottlenecks. Further, recognition of the key elements impacting authorization timelines led to the evolution of data with the introduction of delineated timing data, informally called the "chess clock" at UHN. This data, specifically separates time spent with study teams from time spent with review departments, providing deeper insight into what drives faster review timelines and what contributes to delays. These insights support iterative refinement of system logic and reviewer workflows, while recognizing external influences such as staffing changes and increasing research complexity.

More recently, CAPCR has been integrated with other institutional systems, including Epic (UHN's electronic medical health record), to enhance the safety of patients also participating in research, billing accuracy, and coordination between research and clinical care. Growing data complexity has prompted UHN to invest in analytics expertise, dashboards, and system integrations.

Overall, CAPCR demonstrates how integrated data and metrics can support evidence-based oversight, continuous improvement, and emerging evaluations of Human Research Protection Program (HRPP) effectiveness, addressing long-standing gaps in measuring both the quality and performance of research review systems.

4 Initiatives Shaping the Current Institutional Authorization Workflow

With over a decade of learnings, focus has shifted in the last 4 years to further decrease review timelines and improve stakeholder satisfaction, while maintaining the operational, regulatory, ethical, and institutional standards the IA model was designed and built on. Bottleneck analyses revealed nuances in the review process that existing data could not fully explain. Time-in-review data was useful but lacked the granularity needed to distinguish between delays caused by reviewers and those caused by research teams. In response, the chess clock data metrics were introduced in early 2025, measuring the time reviewers take to raise queries or flag issues alongside the time study teams take to respond. These metrics also describe the iterative nature of queries and how many iterations have taken place during a review. This addition successfully captured the cumulative impact, both study teams and review departments have on review timelines, while also highlighting

that there was a third factor at play, the influence of external contributors that were not always apparent in previously available data.

Notably, median response times from study teams have generally on average been higher than those from reviewers, pointing to a meaningful and previously underappreciated source of delay (see Figure 1). The introduction of the "chess clock" feature enhanced accountability on all sides of the process and helped shift the perspective, that while study teams may view themselves as end users of an established review process, are also active participants in its capacity and overall efficiency. Recognizing this has been an important step in fostering shared responsibility for review timelines across all groups involved. This in turn supported the need for heightened transparency, allowing study teams and review departments alike to better understand their impact and take meaningful action in moving the review process forward. These findings underscored the need for increased and enhanced support for research teams, contributing to the establishment of Clinical Research Units dedicated to helping investigators and study teams navigate the review process and the broader demands of conducting research at UHN.

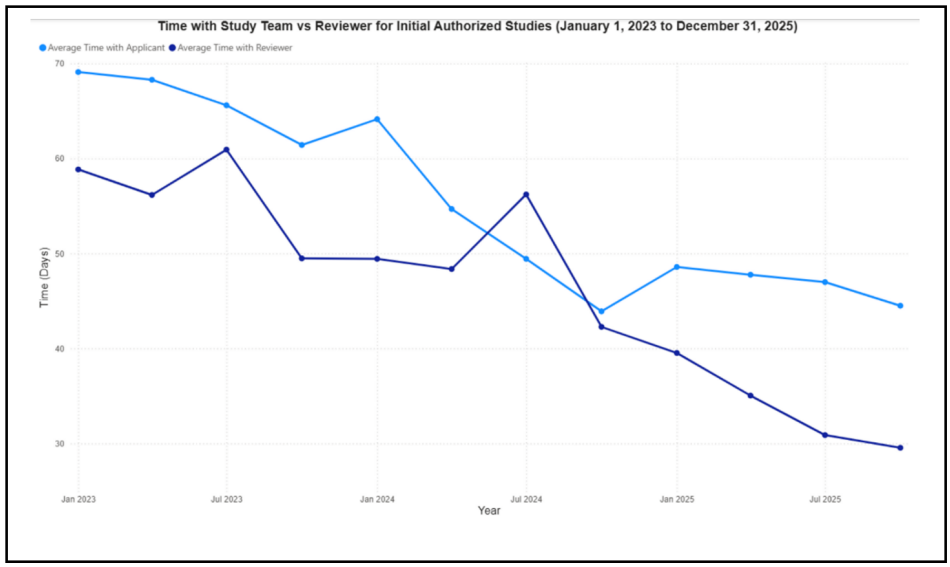

Figure 1. Average time application queries are with the Study Team compared to with a reviewer for Initial Applications Authorized (January 01, 2023 – December 31, 2025)

While the CAPCR system has been successful in enhancing review transparency, providing real-time updates and facilitating communication, the success of these features depended on users regularly logging into the system. In 2022, an initiative was introduced to enhance communication and resolution of outstanding queries and tasks, targeting both study teams and review departments. The goal was to direct attention specifically to outstanding tasks requiring action, rather than adding to the volume of routine informational notifications that users tended to overlook. The initiative also created an

opportunity to capture a new layer of data; contributing factors to common delays. While previous reporting features could identify time with the study team as opposed to when they were with the review department, they could not account for delays attributed to external influences such as Health Canada regulatory approvals or delays related to external sponsors, etc. Delays were further categorized by source, distinguishing between internal and external delays, as well as by type (e.g. staffing changes, or waiting on sponsor responses), making it easier to identify and address bottlenecks earlier in the review process. The result was a 32.5% reduction in time to IA, accompanied by decreases in both time with reviewer and time with study team (see Figure 2). When accounting for outliers, (i.e. studies where there was some extenuating circumstance causing excessive delays), the impact of these initiatives becomes almost 34%.

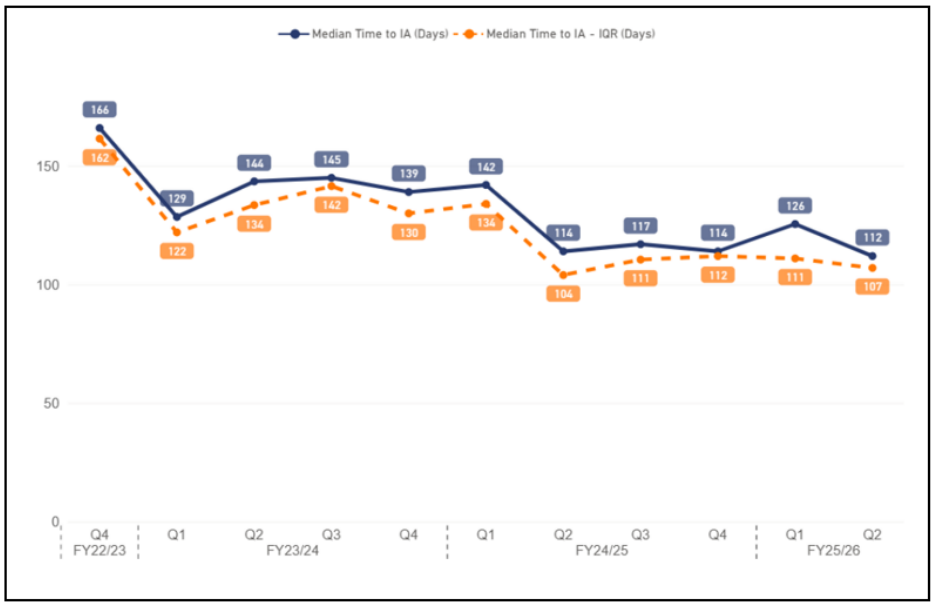

Figure 2. Median Time to IA 2022 /2023 Q4 – 2025/2026 Q2

Building on these results, UHN turned its attention to more fundamental changes in how the review process was structured, further launching IA45, a transformative initiative aimed at reducing the average time to activate a research study to 45 days. Achieving this required commitment across all stakeholder groups and a willingness to rethink longstanding review structures and processes.

A central feature of IA45 is an abbreviated IA process that separates mandatory regulatory and compliance reviews from broader institutional business process and impact assessment reviews. Rather than requiring all reviews to be completed sequentially before IA is granted, the model establishes a dedicated stream for mandatory approvals while allowing other reviews to proceed in parallel or after IA is achieved. This structural change

allowed reviews to be sequenced in a way that better reflected their relative urgency and regulatory necessity, while enhancing efficiency without compromising the rigour of the overall process.

To further accelerate timelines, the IA45 initiative introduced a fast-track lane for industry sponsored clinical trials meeting specific requirements (e.g. regulatory documents in place, use of templated agreements, etc.). This stream standardized expectations for all reviewers, enabled Principal Investigators (PIs) to identify and recommend priority studies, and provided review departments with clarity on where to focus effort and resources. For studies that qualify, an attestation or opt-out model was also piloted, under which implied approval is granted within 28 days if no objection is raised within the first 14 days of submission. This model was applied only to business process and impact assessment reviewers, not to regulatory or compliance reviewers, keeping the approach risk proportionate and balanced. Patterns in implied approvals also offered a practical lens into reviewer capacity, informing decisions about resourcing and support (University Health Network, 2026).

Recognizing that faster timelines are only achievable when research teams are adequately supported, IA45 has been closely aligned with the establishment of the UHN Clinical Research Collaborative Centre, which encompasses site based Clinical Research Units. Through these Clinical Research Units, the Collaborative Centre provides investigators with the infrastructure, expertise, and hands-on support needed to navigate the authorization workflow efficiently. This integration ensures that the drive toward IA in 45 days does not come at the expense of research quality or Human research protection, with key stakeholders supported at every stage of the process.

5 Performing preliminary predictive analysis

To further strengthen the analytical capability of the system, a feature importance analysis was developed to identify which study characteristics have the greatest impact on time to IA, both positively and negatively. Several factors were found to be particularly influential.

By far the largest impact was determined to be the size of the research team (see Figure 3). Studies with larger research teams tended to move through the process more efficiently, as investigators had greater support to carry out the necessary administrative and regulatory tasks. As the risk profile of a study increased, so too did the number of application sections and the number of reviewers required, each adding to the overall review burden. Other complexity indicators included studies regulated by Health Canada which introduced dependency on external regulatory approvals outside of the study team’s or reviewer's control.

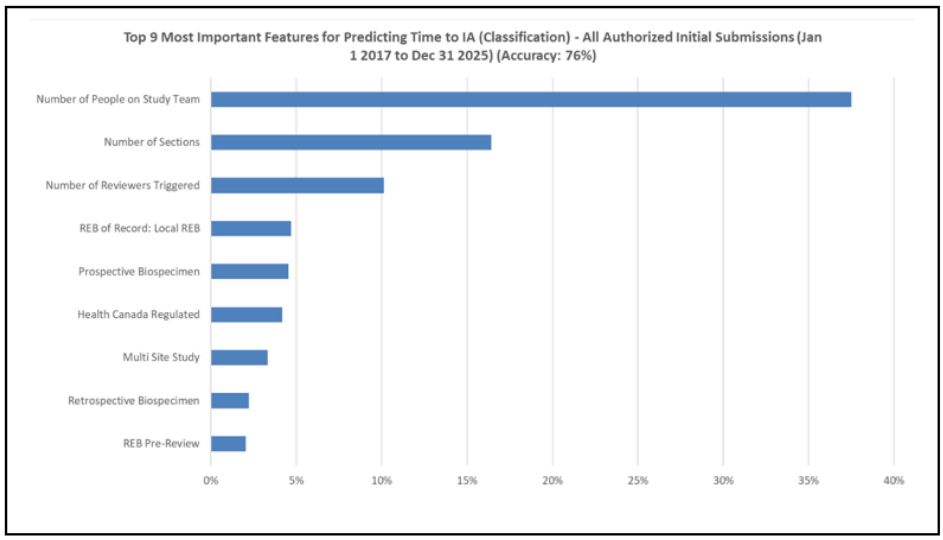

Figure 3. Top 9 Features for Predicting Time to IA (Classification model) of All Authorized Initial Submissions (January 1, 2017 – December31, 2025)

Multisite studies added a further layer of complexity, as external groups needed to enter into agreements before the study could proceed. Biospecimen components, whether prospective or retrospective, introduced their own set of considerations such as consent requirements, the identifiability of the biospecimen, and the varying review pathways that biospecimens may require depending on their classification, all contributed to additional complexity. Similarly, studies subject to REB pre-review, where questions or clarifications were needed before the formal review could begin, may point to whether all submission elements were available at the time of submission or not.

Collectively, these factors point to the inherent complexity of certain study types and help explain the variation in how quickly studies move through the authorization process, with varying combinations adding or removing perceived friction or delay. When layered with the additional time required to obtain responses from study teams, sponsors, or external groups outside the system, the feature importance analysis provides a nuanced and evidence-based picture of what drives delays and where targeted support can have the greatest effect. The insights identified in this initial assessment will serve as a foundation for deeper exploration using expanded predictive analytics tools in future phases.

6 Conclusion

The evolution of UHN's Institutional Authorization model over more than a decade reflects a broader truth about research oversight: administrative systems must be actively managed and continuously improved if they are to keep pace with the growing complexity of clinical research. What began as a response to “ethics creep” and the limitations of local REB review has matured into a sophisticated, data-driven infrastructure that coordinates over 5000 ongoing studies annually, across 5 academic hospitals (Princess Margaret Cancer

Centre, Toronto General Hospital, Toronto Western Hospital, Toronto Rehabilitation Institute, and West Park Healthcare Centre), an education institute (The Michener Institute of Education) along with a governance framework aligned with site and discipline based Research Institutes (University Health Network, 2025).

Several lessons emerged from this experience that may be useful to other large academic health networks. First, separating ethical review from institutional compliance review is not merely an administrative convenience; it is a structural safeguard that protects the independence of REBs while ensuring that non-ethical risks are still appropriately managed. Second, UHN's investment in CAPCR as a reporting and analytics tool, not just a workflow system, has been central to its ability to identify problems, test solutions, and measure outcomes. Third, meaningful reductions in review timelines require understanding where time is actually being lost.

The introduction of the “chess clock” data demonstrated that study teams, not just review departments, are a significant source of delay, a finding that would not have been visible without granular measurement. Further, making this data visible to all parties created a new level of accountability, giving both study teams and review departments a clearer understanding of their respective impact on the process and a stronger basis for action. The IA45 initiative represents the current evolution of this work, applying structural process redesign, fast-track pathways, and proportionate parallel review streams to achieve institutional authorization within 45 days. Early results are promising, and the model continues to evolve in response to data and stakeholder feedback.

Ultimately, the goal of all these efforts is not simply speed for its own sake, but also to ensure that important research outcomes can reach patients faster for greater impact, that investigators can focus on science rather than administration, and that the systems designed to protect research participants remain rigorous, independent, and trusted (Coulter et al., 2023; Hong et al., 2024). The UHN experience suggests that with the right infrastructure, the right data, shared accountability, and sustained institutional commitment, these goals are achievable together rather than in tension with one another.

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