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IRB ANNUAL REPORT 2025

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SUMMARY

The purpose of this annual report is to promote transparency and accountability in the IRB's operations, document its activities and impact, and provide prospective clients and partners with insight into its ethical review processes, expertise, and commitment to high-quality research oversight. In 2025, the Includovate Institutional Review Board (IRB) continued to strengthen its commitment to promoting high-quality, ethical research while safeguarding the rights, dignity, and well-being of all research participants. Central to this mission is the IRB's role not only as an oversight body, but as a collaborative partner supporting researchers in designing and implementing ethically sound and inclusive studies.

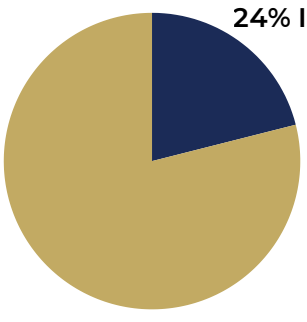
The IRB operated in 2025 under the leadership of Chair **Natalia Pastori Curbelo** and Vice Chair **Andrea Mrazova,** with strategic oversight provided by Research Director **Melissa Langworthy**. The IRB includes leadership from low- and middle-income countries to ensure that research oversight reflects local priorities, cultural context, and the perspectives of communities most affected by the studies.
Includovate's IRB is designed not only to uphold high ethical standards but also to support innovative and inclusive research methodologies, including indigenous, participatory, and community-based approaches. Its diverse and globally representative membership helps ensure that ethics review processes are responsive to different cultural contexts, knowledge systems, and lived experiences. This approach reflects Includovate's broader commitment to decolonising research and promoting ethical oversight that is both rigorous and contextually relevant.

COMPOSITION & DIVERSITY OF THE IRB

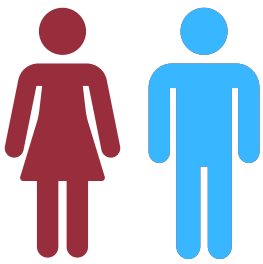
As of January 2026, the IRB comprised 17 members representing a wide range of geographic regions, including Africa, Asia, Europe, the Americas, and Australia. The board's diversity spans multiple dimensions, including gender, age, disciplinary expertise, and professional background. Members include legal experts, community leaders, activists, PhD-level researchers and healthcare professionals.

Current IRB Members: 17

Member Type



Gender Breakdown



Female: 14
Male: 3

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The gender composition of the IRB includes 14 women and 3 men, while approximately 12% of members identify as persons with disabilities. This diversity is a defining strength of the board, enabling more nuanced and context-sensitive ethical review processes. The IRB's diversity is integral to its identity, allowing it to function as an oversight body, as well as a partner in fostering more equitable and accessible research practices.

Geographic Coverage

America: 4

Asia: 4

Africa: 5

Australia: 1

Europe: 3

12%

Persons with Disabilities

OVERVIEW OF APPLICATIONS REVIEWED

During 2025, the IRB reviewed and approved 11 full standard research applications and 2 expedited review applications, for a total of 13, a slight increase from 2024 (11 applications in total). Of these, 7 were internal submissions from Includovate-affiliated researchers, while 6 were external applications from organisations or independent researchers. Each application underwent rigorous ethical review in accordance with established IRB procedures, with particular attention to participant protection, methodological soundness, and inclusivity. Includovate IRB is registered with the Office for Human Research Protections and adheres to globally recognised ethical frameworks, including the Common Rule, The Belmont Report and The Declaration of Helsinki.

STRATEGIC DEVELOPMENTS AND PROCESS IMPROVEMENTS

In 2025, the IRB undertook several significant strategic updates to improve efficiency, clarity, and impact. One major development was the formalisation of differentiated review pathways. These now include: standard full reviews, resubmission reviews, expedited reviews (Type A for minor changes without tool modifications and Type B for minor changes involving tools), and full re-reviews for substantial changes or expired approvals. These categories have improved the efficiency and consistency of the review process.

Recognising that ethical oversight extends beyond initial protocol review, the IRB also introduced a more robust post-approval monitoring system. This includes ongoing monitoring of approved studies, establishing annual review meetings, and producing annual reports summarising key insights and lessons learned. Additionally, new templates were developed to support both internal and external monitoring processes, enhancing standardisation and accountability.The standardisation of internal and external monitoring processes was introduced to ensure consistent oversight of all approved studies, strengthen documentation and follow-up procedures, and enhance transparency. By establishing clear monitoring and reporting mechanisms, the IRB has improved accountability to research participants, communities, clients and funders.

To improve accessibility and inclusivity, the IRB expanded its language capabilities and began accepting applications in Portuguese, French, and Spanish through a primary reviewer system. This represents an important step toward reducing language barriers in ethical review processes.

Internal governance was also strengthened through the review and updating of IRB guidelines and procedures. Furthermore, the IRB reintroduced reimbursement for CITI training certification for all members, recognising the importance of continuous professional development in maintaining high ethical standards.

KEY CHALLENGES AND LESSONS LEARNED

The review of applications throughout the year revealed four recurring challenges that have informed key lessons and improvements to IRB processes and guidance.

1. Applications frequently showed gaps in defining compensation for participating in the study, often lacking clear details on the amount, timing, and justification of compensation. The IRB stressed that remuneration must be ethically justified and proportionate to participants' time and burden, without acting as undue inducement. **Clear distinctions between reimbursement and incentives are essential because they ensure there is no undue influence on participation. Appropriate levels depend on the participant's country and contextual circumstances; accordingly, the IRB requires clear criteria for determining reimbursement, defined on a study-by-study basis and transparently communicated to participants to support ethical consistency, informed consent, and efficient review.**

2. Many applications failed to clearly specify participant eligibility, with vague inclusion and exclusion criteria. The IRB emphasised that **precise definitions—covering characteristics such as age, gender, and other relevant factors—are necessary to ensure transparency and support the ethical review process.**

3. Inconsistencies across research tools and documentation were a recurring issue, with misalignment among protocols, consent forms, and data-collection instruments. Where differences exist between study groups (e.g., control and intervention groups), these must be clearly justified. **Misalignment raises concerns about data validity, participant understanding, and fairness, and often leads to delays from revision requests.**

4. IRB also raised concerns about insufficient safeguards for vulnerable populations, such as children and persons with disabilities, underscoring the need for additional protections, appropriate consent procedures, and explicit risk minimisation. For children, sufficient safeguards include obtaining both parental consent and child assent, as well as using age-appropriate communication. For persons with disabilities, considerations must include accessibility, capacity to consent, and reasonable accommodations. An additional cross-cutting issue raised during the year was the limited attention to gender diversity, particularly regarding non-binary identities. Some applications, especially those originating from contexts with limited gender-disaggregated data, did not adequately address these dimensions. **While recognising contextual constraints, the IRB emphasised the importance of striving toward more inclusive research practices.**

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LOOKING AHEAD

Looking forward, the IRB remains committed to strengthening its role as an independent and reflective body that not only ensures compliance with ethical standards but also actively contributes to the evolution of ethical research practices. The fact that the IRB has obtained six external clearances indicates that it is addressing an unmet need in the market by providing a trusted, recognised ethics review mechanism that complements existing structures. A key priority is to continue addressing what has been termed “IRB coloniality,” specifically the tendency of ethical review processes to replicate global North norms at the expense of local knowledge systems. Includovate’s IRB does this by fostering more inclusive approaches and supporting innovative and indigenous methodologies, thereby contributing to more equitable research practices. In 2026, the IRB plans to expand its membership to ensure it continues to reflect and effectively cover the full breadth of contexts and include members from low-income communities in which the research it reviews takes place.

Guided by its mission and vision, the Includovate IRB seeks to foster ethical research governance that is responsive, inclusive, and reflexive, supporting researchers in conducting studies that are methodologically sound and attentive to social and contextual realities.

It is a pleasure to work with you. I appreciate the care taken by you and the quick responses and turnaround."

– (Health preference study - Pfizer)

We sincerely appreciate your valuable recommendations. They will help us ensure we uphold high ethical standards and accountability to the communities we serve."

– (ICRC Evaluation Africa)

CONTACT US

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