



Position Statement: Moving Beyond the 3Rs Framework in Animal Research

Animal Alliance of Canada & the Advisory Group on Humane Science

For over six decades, the 3Rs—Replacement, Reduction, and Refinement—have formed the cornerstone of animal welfare policy in research. The Principles of Humane Experimental Technique¹ originally represented a progressive step to minimize animal suffering. However, the scientific landscape and public ethical expectations have evolved dramatically since 1959.

Modern technologies (e.g. organ-on-chip systems, AI modelling, human-cell micro physiological platforms) and new insights into animal cognition and sentience have revealed that the 3Rs framework is no longer sufficient on its own.² Rather than prompting a transition to innovative non-animal methods and ethical community partnerships, the traditional 3Rs emphasis on incremental harm-reduction often ends up validating the status quo and treating animals as mere instruments for human benefits.³

Ontario’s policymakers have a critical opportunity to modernize ethical oversight of animal use in science. A more robust framework is needed—one that goes beyond minimizing harm to questioning animal use, prioritizing human-relevant research methods, and ensuring transparency and accountability. This will earn public trust, align with contemporary science, and uphold the values of 82% of Canadians⁴ who believe that all

¹ Russell, W. M. S., and R. L. Burch. *The Principles of Humane Experimental Technique*. London: Methuen & Co., 1959.

² Bertrand, Kati. “*Exposing the Gaps: How the 3Rs Fail to Protect Animals in Research.*” Reflections, *Science Advancement and Outreach Division*, November 2024. Accessed February 11, 2026. <https://www.scienceadvancement.org/reflections/exposing-the-gaps-how-the-3rs-fail-to-protect-animals-in-research/>

³ *Ibid.*

⁴ Canadian Council on Animal Care, “*2024 Opinion Poll Results on the Use of Animals in Canadian Science,*” *News and Media*, February 20, 2025, <https://ccac.ca/en/about/news-and-media/2025/02/20/2024-opinion-poll-results-on-the-use-of-animals-in-canadian-science/>



organizations using animals for medical and scientific purposes in Canada should be mandated to adhere to an ethical standards and oversight system.

The 3Rs Do Not Ensure Ethical Justification of Animal Use

A core deficiency of the 3Rs is that they presume *a priori* that animal experiments are acceptable so long as procedures reduce harm. The framework does not require researchers or institutions to justify whether using animals is ethically or scientifically necessary in the first place. In Ontario, animal care committees apply 3Rs to refine protocols, but there is typically *no mandate to ask whether the entire animal-based study should even happen*. As a result, experiments with marginal scientific value or poor translational relevance can proceed as long as they use “the fewest animals possible” and “improve welfare” in minor ways. It is a common, yet incorrect, assumption by members of the public that a researcher will assess the merit and necessity of animal use, not just its minimization of suffering.

Under Canada’s current system, there is no mandatory animal ethics review.

Although CCAC guidance frames protocol review as a harm-benefit assessment and requires institutional animal care committees to be satisfied that animal use is justified, these determinations are made internally, with variable standards and limited external accountability.⁵ Granting agencies assess scientific merit separately from ethical cost, and there is no publicly auditable demonstration that expected benefits truly outweigh animal harms. In practice, projects that secure funding and meet basic 3R requirements are rarely rejected on ethical grounds.⁶ The system therefore risks treating compliance with procedural standards as sufficient justification, rather than demanding rigorous proof of necessity and superior benefit.⁷ Modern ethics requires asking not only “How can we do this experiment humanely?” but “Should we do it at all, given the harms?”

⁵ Vaughan Black, Andrew Fenton, and Elisabeth H. Ormandy, *Protecting Canada’s Lab Animals: The Need for Legislation*, *Animals (Basel)* 12, no. 6 (2022): 770, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8944469/>

⁶ *Ibid.*

⁷ *Ibid.*

The 3Rs Framework Overlooks Scientific Rigor and Public Benefit

Projects can comply with 3R guidelines yet still lack scientific rigor or societal value. The 3Rs focus on *how* to conduct a given experiment, not on *if the experiment is ethically worthwhile*. That is, a study could use a smaller number of animals (Reduction) and better pain management (Refinement) and still be poorly designed, not reproducible, or irrelevant to real-world outcomes. Such work wastes resources and lives without delivering public benefit. Given the public outrage over studies conducted on dogs⁸ at St. Joseph’s Lawson Research Institute in London, Ontario, it is clear the public believes policymakers should ensure that animal-based research undergoes strict necessity and relevancy tests – for example, by requiring robust scientific merit review *integrated with* ethics review – so that only studies with compelling justification and sufficient oversight and transparency proceed.

At present, the burden is more often on innovators to prove a non-animal method is valid, rather than on animal users to prove an animal model is truly needed. Ethical governance must shift the default in favour of modern, humane, and human-relevant methods. If an animal study’s objectives can likely be met with cell-based, computational or other advanced approaches, or if the likely knowledge gain is trivial, continuing with animal use should be deemed unacceptable.

Replacement – The Unrealized Priority

Replacement (substituting animals with non-animal methods) is the most ethically crucial of the 3Rs, yet it remains the least implemented in practice. Despite community partnerships and breakthroughs in technologies, such as *in vitro* biology, in silico modelling, and bioengineered human tissues, animal models persist as the default in biomedical research and toxicity testing. This persistence reflects institutional inertia, bias, and habit, not scientific necessity.⁹ In many cases, researchers continue with animal experiments even *when validated non-animal alternatives exist*, due to comfort with traditional methods and a lack of incentives to change.¹⁰ The result is that, in Canada, the

⁸ Jenna Olsen and Robert Cribb, “Puppies Secretly Tested and Killed at Ontario Hospital for Human Heart Research,” *Investigative Journalism Bureau* (IJB), August 7, 2025, <https://ijb.utoronto.ca/news/dog-testing-london-hospital/>

⁹ Bertrand, “*Exposing the Gaps.*”

¹⁰ *Ibid.*



overall use of animals in research, teaching, and testing has not declined in recent years.¹¹ It has, in fact, increased and remains higher than in countries with significantly larger populations. CCAC data show animal use in CCAC-certified institutions increased from 3,128,943 (2023) to 3,706,907 (2024), an ~18.5% rise year-over-year.¹²

Animal Alliance of Canada and the Advisory Group on Humane Science assert that full replacement of animal use must become an explicit policy goal, not merely a distant aspiration. Replacement should no longer be interpreted as “use non-animal methods *when convenient*.” It should be the expected default approach. Canada’s research institutions and regulators should require that new approach methodologies (NAMs) be used wherever they are available and applicable, with animal use permitted only through exception when absolutely necessary and justified openly. This means investing in and fast-tracking modern methods so they can fully replace outdated animal tests.

Notably, recent U.S. and European regulatory shifts are accelerating this transition – for example, the U.S. *FDA Modernization Act 2.0* (2022) ended a federal mandate for animal testing in drug development, recognizing that advanced alternatives can ensure safety and efficacy.¹³ In 2025, the U.K. government unveiled a detailed strategy to phase out many animal tests by specific dates, backed by millions of dollars in funding for alternatives like organ-on-chip and AI models.¹⁴ Ontario could position itself as the Canadian leader in this global shift. By mandating and prioritizing human-relevant, non-animal science, Ontario can spur innovation, improve the reproducibility of research, and better protect both animals and research participants.

¹¹ Black, Fenton, and Ormandy, *Protecting Canada’s Lab Animals*.

¹² Canadian Council on Animal Care, “Explore the CCAC Animal Data Report 2023,” *News and Media*, December 17, 2024, <https://ccac.ca/en/about/news-and-media/2024/12/17/explore-the-ccac-animal-data-report-2023/>; and Canadian Council on Animal Care, “Explore the CCAC Animal Data Report 2024,” *News and Media*, October 9, 2025, <https://ccac.ca/en/about/news-and-media/2025/10/09/explore-the-ccac-animal-data-report-2024/>

¹³ Steven B. Krewski et al., “Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States,” *Journal of Toxicology and Environmental Health, Part B* 24, no. 3 (2021), <https://pubmed.ncbi.nlm.nih.gov/36762462/>

¹⁴ Department for Science, Innovation and Technology, Department for Environment, Food & Rural Affairs, Home Office, and Lord Vallance, “Animal Testing to Be Phased Out Faster as UK Unveils Roadmap for Alternative Methods,” GOV.UK, November 11, 2025, <https://www.gov.uk/government/news/animal-testing-to-be-phased-out-faster-as-uk-unveils-roadmap-for-alternative-methods>

Reduction – Necessary but Not Sufficient

The principle of Reduction aims to use fewer animals to obtain a given amount of information. In practice, efforts to reduce animal numbers per study or overall are only modestly applied and can sometimes be misleading. Slight numerical reductions often occur without changing the reliance on animal models. For example, laboratories may use five animals where they once used ten but continue conducting dozens of animal-based projects overall.

Moreover, an overly narrow pursuit of reduction can create new problems: studies with too few animals may yield inconclusive data, necessitating follow-up experiments that use even more animals in total.¹⁵ In some cases, focusing on minimizing animal count can conflict with animal welfare (Refinement) if, for example, a protocol uses fewer animals *but subjects each to greater interventions*.¹⁶ These “3R dilemmas” illustrate that Reduction alone does not guarantee ethical or scientific improvements.¹⁷

We support efforts to eliminate unnecessary duplication of animal use and to improve experimental design (e.g. better statistics, sharing of data to avoid repeating tests). Indeed, avoiding redundant animal experiments is crucial – currently, Canada’s fragmented oversight means researchers at different institutions might unknowingly replicate the same animal studies, causing additional suffering and wasting lives and resources.¹⁸ However, Reduction should be seen as a *transitional strategy*, not a permanent pillar of scientific practice. The true metric of progress is not just “using fewer animals per experiment,” but replacing animal-based experiments altogether with *more effective* methods.

Refinement – Important Improvements but Inherent Harms Remain

Refinement involves modifying animal use to minimize pain, stress, and suffering – for example, better housing and enrichment, improved anesthesia and analgesia, or using less invasive techniques. These welfare improvements are certainly important; however, Refinement alone cannot resolve the deeper moral and scientific problems of using sentient beings as research tools. Even under the best conditions, laboratory animals

¹⁵ Bertrand, “*Exposing the Gaps*.”

¹⁶ *Ibid.*

¹⁷ *Ibid.*

¹⁸ Black, Fenton, and Ormandy, *Protecting Canada’s Lab Animals*.

experience harms that refinement cannot eliminate - confinement, removal from natural social structures, invasive procedures, and almost always death at experiment's end. These are “built-in” harms of animal research that no amount of cage enrichment or painkiller can fully mitigate.

Refinement measures also do not address the core issue of animals' moral status. An experiment that keeps animals comfortable up until a harmful procedure still raises the question of whether it is right to impose that procedure on them at all. Ontario's new policy framework must acknowledge that *reducing* suffering is not the same as justifying the act of causing suffering for research aims. From a scientific perspective, Refinement cannot overcome the biological differences that often make animal data poor predictors of human outcomes. A highly Refined experiment on rats may still fail to translate to human medicine because rats are not humans. The goal should be to make Refinement moot by obviating the need for animal use entirely.

Current Oversight Lacks Transparency and Public Accountability

Canada's system for oversight of animal research defers responsibility to institutional committees operating behind closed doors. The Canadian Council on Animal Care (CCAC) guidelines, which some research facilities follow, are voluntary and self-regulating – they are not bound by law and carry no public reporting requirements beyond high-level aggregate statistics. Consequently, most animal experimentation in the country occurs with minimal transparency.¹⁹ Detailed information about experiments is not readily available to the public. Even when CCAC assessors and Ontario's provincial inspectors find non-compliance with guidelines or provincial regulations, the details are not disclosed and, in the case of the CCAC, are kept confidential.²⁰ The 3Rs framework itself is silent on issues of transparency or external accountability; it focuses solely on what researchers should do, not on what they must disclose.

Democratic oversight is effectively missing under the 3Rs status quo. **There is no independent authority in Canada tasked with ensuring ethical use of animals in science.** If a member of the public or an MPP has concerns about a particular animal experiment, there is no clear, politically accountable body to approach. The lack of a legislated mandate means questions often bounce between agencies with no one taking

¹⁹ *Ibid.*

²⁰ *Ibid.*



responsibility. This stands in contrast to human research, which has external ethics boards and legal frameworks, or to jurisdictions like the U.K. where a government department publishes reports on infractions.²¹

Ontario's approach must advance by establishing greater transparency and accountability mechanisms beyond the internal animal care committees. This could include public databases of approved projects, mandatory publication of animal use statistics with trend data, independent inspections and unannounced visits, and infractions and corrective actions. Without such measures, the public is unaware of whether the 3Rs are being rigorously applied, or that ethical standards are truly being enforced. As public support for animal research erodes, maintaining secrecy will only further diminish trust. True accountability and openness are now non-negotiable components of ethical science governance.

The 3Rs Ignore Evolving Understandings of Animal Sentience and Value

The 3Rs treat animals primarily as tools whose welfare should be managed, rather than as individuals with their own interests and rights.²² The framework contains no principle that says “do not use animals who are capable of suffering if it isn't morally justified” – it simply assumes animal use is acceptable if refined. This is increasingly at odds with evolving public expectations. Indeed, the Ontario government's recent Bill 75 (2025) – part of which seeks to ban most invasive research on dogs and cats – arose precisely because public and scientific consensus deemed those practices no longer tolerable given the availability of non-animal methods.

A modern ethical framework for research should explicitly incorporate respect for animals' sentience. This could mean, for example, categorically prohibiting certain severe experiments on any animal capable of suffering, or disallowing the use of species like dogs, cats, and primates. In addition, it would also mean prohibiting the use of any animal research where non-animal alternatives exist and aligning animal research ethics with principles similar to those in human research (e.g. recognizing subjects' inherent

²¹ *Ibid.*

²² Bertrand, “*Exposing the Gaps.*”



value and interests). While animals cannot consent, we *can* ensure that their vital interests (avoidance of pain, living in natural conditions, etc.) are given weight in decisions.

Toward a New Humane Science Framework

It is clear that simply reinforcing the 3Rs will not deliver the transformative change needed in animal-use policy. We call for a fundamentally different paradigm – one that treats animal use as a last resort, embeds independent ethical scrutiny at every level, and actively drives the replacement of animals with better methods.

Key elements of this framework should include:

- **Mandatory Prioritization of Non-Animal Methods (NAMs):** A NAM-default decision standard must be established. Government agencies, research funders, and institutional review boards must require the use of validated non-animal techniques wherever available. Animal use should not be the starting assumption; instead, any proposal involving animals should trigger a heightened justification process demonstrating scientific necessity and absence of suitable alternatives. Regulators should also create accelerated pathways to validate and accept new alternative methods. For example, if an organ-on-chip or computer model can predict a toxicological outcome, it should be swiftly incorporated into guidelines so that the animal test it replaces is no longer permitted. We have seen internationally that clear mandates work – e.g. the U.S. FDA’s roadmap and the U.K.’s detailed commitments to phase out specific animal tests are already pushing researchers to pivot to alternatives.²³ Were this approach implemented, Ontario is well-positioned to be the leader in Canada.
- **Independent and Transparent Oversight:** The self-regulating model of animal care committees should be replaced or supplemented with *truly independent* oversight mechanisms. This could involve a provincial oversight board or inspectorate with legal authority to audit facilities and to enforce regulations (rather than relying on

²³ Department for Science, Innovation and Technology et al., “*Animal Testing to Be Phased Out Faster as UK Unveils Roadmap for Alternative Methods*,” GOV.UK, November 11, 2025, <https://www.gov.uk/government/news/animal-testing-to-be-phased-out-faster-as-uk-unveils-roadmap-for-alternative-methods/>

voluntary compliance). Public accountability must be built in: regular publication of inspection results, infractions, and the outcomes of ethics reviews should be required.²⁴ Crucially, the province should assign clear political responsibility for animal research oversight so that elected officials can be questioned and held accountable for how animals are used in science.

- **Sunset Timelines for Animal-Based Methods:** A necessary element is to set legislated timelines to phase out categories of animal use, especially where alternatives exist. This is the approach of many jurisdictions: the European Union is developing a plan to phase out animal testing in chemicals and research; the U.S. Environmental Protection Agency had a target (since updated) to eliminate mammalian testing by 2035; and as noted, the U.K. has committed to specific goals by 2026, 2027, or 2030 in certain areas.²⁵ Canada must work towards setting a legally binding expiry date on archaic toxicology tests (beyond a policy commitment), replacing them with high-throughput NAMs. Setting clear end-dates focuses efforts and signals to researchers and industry that investment must shift to new methods.
- **Investment in Humane, Human-Relevant Science:** To support this transition, significant investment is needed. We urge federal and provincial governments to shift funding programs from animal to non-animal research methods. This includes grants for developing organ-on-chip devices, computational modelling platforms, 3D-bioprinted tissue projects, and other NAM technologies, as well as training programs to equip scientists with the skills to use them. Investing in this infrastructure not only facilitates the reduction of animal use but also presents an economic opportunity: the global market for alternative methods is growing rapidly, and Ontario can capture part of that market by being the Canadian leader in NAM research and manufacturing.
- **Cross-Disciplinary Collaboration:** Transitioning to a new framework for research ethics requires inclusive collaboration. We urge the formation of a provincial task force or working group on humane science innovation, bringing together diverse stakeholders: scientists from academia and industry, ethicists, healthcare

²⁴ Black, Fenton, and Ormandy, *Protecting Canada's Lab Animals*.

²⁵ GOV.UK, "Animal Testing to Be Phased Out Faster."



professionals, government regulators, Indigenous knowledge-holders (who can offer valuable perspectives on our relationship with animals), as well as public interest groups and animal advocates. This group could develop a roadmap for phasing out animal use, identifying priority areas and key obstacles. To that end, Animal Alliance has convened an Advisory Group on Humane Science whose members are eager to collaborate with the province. In summary, breaking down silos between sectors and engaging the broader community will be key to moving beyond the 3Rs.

Conclusion

The 3Rs, while historically important, no longer reflect the ethical, scientific, or societal standards of our time. Six decades ago, they were a starting point—not an endpoint. Ontario now has the opportunity and responsibility to chart a path toward a post-animal research era grounded in cutting-edge, human-relevant science and strong ethical principles. This is not a radical change, but a natural progression in line with technological progress and public conscience. Other jurisdictions are already recognizing that a change is inevitable and are actively planning for a future where animal use in science is eliminated.

In practical terms, this means moving beyond the 3Rs as the primary basis for animal research policy. The 3Rs will remain useful as techniques for incremental improvement, but they must be embedded in a larger regulatory framework that first asks, *“Is this animal use justified at all?”* and prioritizes strategies to avoid animal use. We must adopt robust justification requirements, transparent and independent oversight, and rapid implementation of alternatives.

By embracing a modernized framework beyond the 3Rs, Ontario’s policymakers can ensure that research conducted adheres to the highest ethical standards and produces high-quality, human-relevant results. This will safeguard public confidence in science and demonstrate moral leadership.

The Animal Alliance of Canada and the Advisory Group on Humane Science are committed to supporting this transition. We offer our expertise and collaboration to help develop policies that phase out harmful animal use, invest in innovative methods, and elevate



Ontario's research enterprise into a new era of compassion, credibility, and human benefit.

Now is the time to move beyond the limitations of the 3Rs and adopt a framework that truly embodies respect for animals, accountability in science, and a bold vision for humane innovation.