Centre for International
Governance Innovation

Policy Brief No. 217 — November 2025

# A Community-Centred Protocol for Ethical and Scalable AI in Health Care

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## Key Points

- Punitive intellectual property (IP) frameworks and inadequate data sovereignty protections are significant barriers to equitable artificial intelligence (AI) in health care. These barriers disproportionately affect marginalized populations, necessitating urgent reform.
- The authors propose a novel, community-centred AI protocol that integrates FAIR (Findable, Accessible, Interoperable and Reusable) and FHIR (Fast Healthcare Interoperability Resources) standards with flexible IP governance and robust community engagement to address these challenges.
- This approach may be applied through a system that manages IP rights to drive public benefit, as well as a data collective that provides managed access to data so as to prevent misappropriation, and thus effective access to important data that would contribute to greater innovation and access to information within health care.

## Introduction

The integration of AI into health care holds immense promise for enhancing diagnostic accuracy, personalizing treatments as well as optimizing public health systems (Chustecki 2024). However, significant governance challenges threaten to undermine these benefits, particularly for underserved communities. Punitive IP frameworks — overly rigid rules and enforcement practices that prioritize proprietary control over public health needs — restrict access to innovations, especially during crises, while inadequate data sovereignty protections risk exploiting vulnerable populations, such as Indigenous groups, eroding trust and perpetuating inequities (Reddy, Fox and Purohit 2019). Moreover, most health-care data remains fragmented, locked in incompatible formats, or restricted by proprietary systems, undermining the quality and scalability of AI tools (Carroll et al. 2020). Removing these barriers is critical because they limit the equitable dissemination of AI tools and compromise the ethical use of data, which is central to fostering a

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trustworthy and equitable IP governance ecosystem — especially as AI becomes a common good. As AI technologies increasingly permeate every aspect of society, ensuring broad, fair and inclusive access becomes not just a matter of innovation but also of social justice. Treating AI as a common good underscores the urgency of dismantling structural barriers, promoting transparency and fostering collaborative frameworks that prioritize public benefit over proprietary control.

Despite advancements in identifying ethical and regulatory challenges in AI-based health care, the literature reveals a persistent gap in developing integrated frameworks that harmonize IP management with data sovereignty protections, particularly to ensure equitable access for underserved and Indigenous communities (Pham 2025). Furthermore, there is limited research on community-centred protocols that incorporate data collectives to prevent exploitation while fostering sustainable innovation, leaving a critical void in actionable strategies for treating AI as a common good in public health systems (Aaronson 2024; Cordes et al. 2024). Further, few studies offer operational models that reconcile the tensions between proprietary control and equitable access, particularly in the context of AI deployment across marginalized health-care systems. There is also a lack of concrete, community-led governance structures that embed IP and data justice principles into AI design and implementation.

This work builds upon existing literature on AI ethics, data sovereignty and governance challenges by addressing these gaps through a novel, practical approach that emphasizes community involvement and balanced IP management (Pham 2025). To overcome these systemic issues, the authors propose a community-centred AI protocol that serves as a digital bridge across the health-care ecosystem (Mittelstadt 2019). By *community-centred*, the authors mean an approach that systematically integrates community priorities, rights and oversight into governance structures, while balancing technical and policy inputs from governments, institutions and industry. Unlike *community-led* initiatives, which place full leadership and decision-making authority in the hands of communities, a *community-centred* model ensures that communities remain at the core of decision making but within a broader multi-stakeholder framework that aligns resources, expertise and protections with community values.

# Governance Barriers and Challenges

## Rigid and Opaque IP Frameworks

Current IP frameworks, designed to protect the market positions of established players, often impede the equitable dissemination of AI tools in health care by prioritizing vested proprietary interests over public health needs. These rigid structures create barriers to access, particularly in low-resource settings or during public health emergencies where rapid deployment is critical. For instance, during the COVID-19 pandemic, proposals for access to publicly funded solutions via temporary IP waivers under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), led by India and South Africa, highlighted the tension between entrenched proprietary rights and global health demands (World Trade Organization [WTO] 2021). In AI, proprietary algorithms, such as those used in diagnostic models, are protected by thickets of patents and covetous trade secrets, significantly limiting their availability to wealthier nations and communities and making them rarely available to the majority of developing countries (concentrated in the Global South) due to lack of capital, knowledge and technology, which exacerbates health disparities (NITI Aayog 2018). The limited impact of the World Health Organization's (WHO's) COVID-19 Technology Access Pool (C-TAP), alongside the underperformance of the COVAX initiative, highlights the gap between global health equity rhetoric and the structural realities of IP governance, where voluntary mechanisms failed to ensure fair vaccine access for low- and middle-income countries (Eccleston-Turner and Upton 2021). The COVID-19 pandemic has provided strong evidence that complex patenting processes for AI algorithms often involve abstract concepts, hindering smaller innovators and creating monopolies that impede cost-efficient production and progress (World Intellectual Property Organization [WIPO] 2022; Yanisky-Ravid and Jin 2020). Without systematic reforms, such as improved freedom to operate, public benefit frameworks and internationally accessible licensing for health-related AI, these barriers will continue to restrict access and limit innovation. Such barriers to accessing data about health care-related IP may be overcome by implementing systems that provide access to a data collective of IP pertaining to health-care innovations worldwide in an organized, managed way.

## Data Sovereignty and Community Rights

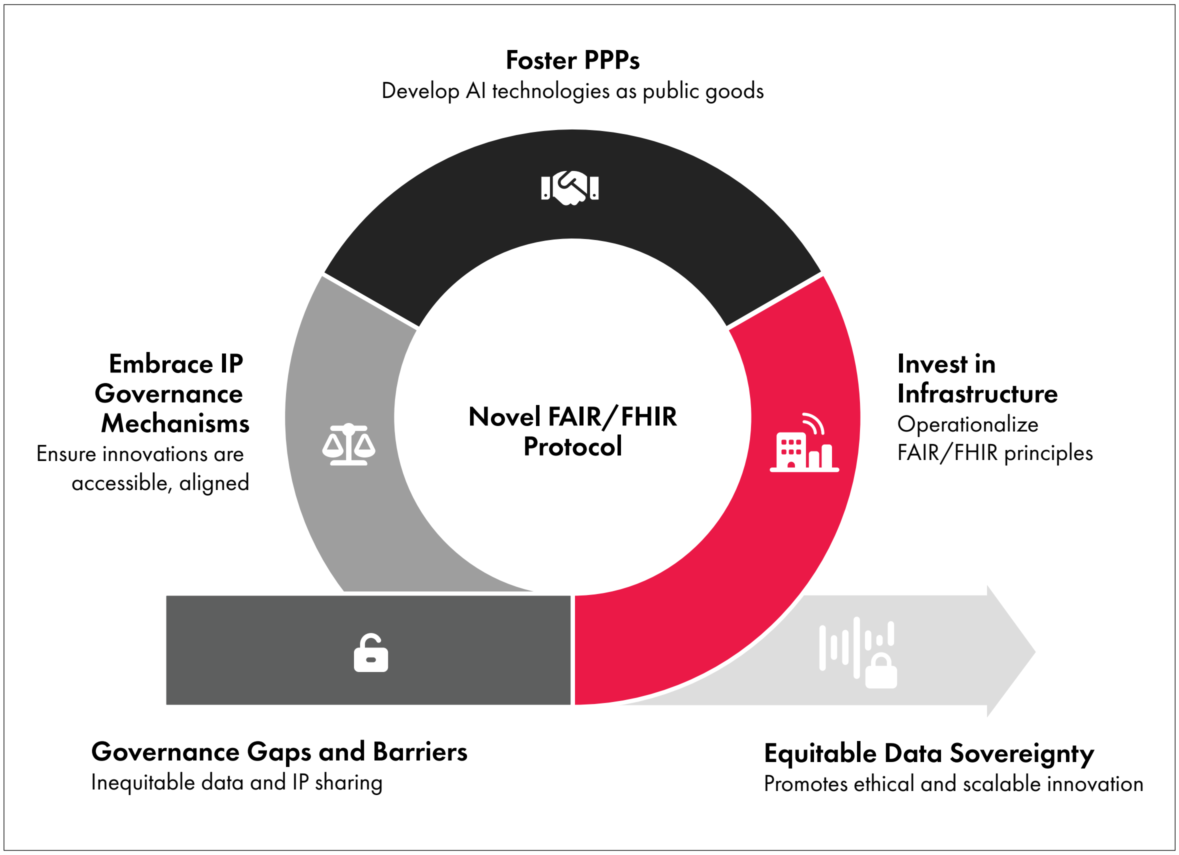
Data sovereignty, the right of communities to control their health data, is a cornerstone of the ethical development and use of AI in health care (Hudson et al. 2020). However, current governance often fails to protect it, risking exploitation and mistrust, particularly among Indigenous and marginalized groups. The 2016 data-sharing agreement between the Royal Free London National Health Service Foundation Trust and Google DeepMind, which involved transferring 1.6 million patient records without obtaining adequate consent, violated the United Kingdom's Data Protection Act and eroded public trust (Powles and Hodson 2017; Taylor and Wilson 2020). Such incidents underscore the need for robust data governance that respects community autonomy. Inadequate governance also risks biased AI models; non-representative training data can lead to poor performance for under-represented groups, perpetuating health disparities (Thomasian, Eickhoff and Adashi 2021). Cross-border data flows further complicate sovereignty, with risks of "ethics shopping" where companies exploit weaker regulations (Morley et al. 2022). Due to the lack of an adequate and transparent data governance framework, with little or no government or corporate accountability, many Indigenous communities are protective of their data sovereignty (Cordes et al. 2024). Strong data governance is vital in preventing data exploitation, ensuring privacy and building trust in AI systems. Data sovereignty may be respected through governance implemented by systems that manage IP and provide access to IP in data collectives containing health care-related IP.

## Proposed Governance Framework

Establishing a community-centred governance framework that promotes data sovereignty for communities and equitable IP sharing and access could offer an effective and inclusive approach to addressing governance gaps and barriers (Yazdinejad and Kong 2025; Whittlestone et al. 2019). The authors propose a novel protocol that acts as a digital bridge across the health-care ecosystem — anchored in two foundational standards: FAIR and FHIR. This protocol facilitates seamless, AI-ready data exchange with curated use of IP through the systemization of algorithms, codes, patents and data for health care, while promoting ethical and scalable innovation. Establishing this governance framework requires a fundamental shift that promotes AI as a public good in health care and beyond. As presented in Figure 1, this framework places a novel FAIR/FHIR-based protocol at the core of equitable and scalable AI governance. It addresses key governance gaps — including inequitable data access and predatory IP regimes — by embedding ethical IP mechanisms, fostering public-private partnerships (PPPs), investing in FAIR-compliant infrastructure and promoting community data sovereignty. The protocol operationalizes technical and ethical standards to ensure AI systems are both inclusive and public-good oriented.

Governments and international organizations, such as the WHO and the Group of Seven (G7), should invest in initiatives that make AI (IP and data) publicly available in a data collective for the public good and police these available systems against appropriation. This includes building and supporting technical infrastructure that operationalizes FAIR and FHIR principles to enable secure, privacy-preserving and standardized data sharing across jurisdictions. Through a data collective, IP rights must be managed for curated usage and access to IP, while respecting such principles, to drive public benefit. This initiative fosters PPPs to develop AI technologies as public goods, ensuring equitable access and benefit sharing, while systematically respecting IP rights and protections. Additionally, the protocol embeds responsible and flexible IP governance mechanisms — such as open-source

Figure 1: A Community-Centred Governance Framework for Ethical AI in Health Care



*Source:* Created by Abbas Yazdinejad.

licensing, rapid-use waivers during crises and community-benefit sharing agreements — to ensure innovations are not only accessible but also aligned with collective values. These may be managed through the use of IP rights management systems and data collectives, which provide organized access to IP that works around IP rights through waivers, community benefit-sharing agreements and so on. The success of open-source tools during the COVID-19 pandemic, such as the COVID-19 Health Inequalities Monitoring in England tool (CHIME), speaks to the effectiveness of this approach. The CHIME tool is designed to collect data on the direct impacts of COVID-19 on key factors, including mortality rates, hospital admissions, confirmed cases and vaccinations (Office for Health Improvement and Disparities 2021). Measurement could be achieved by assessing the increase in publicly available AI tools and their adoption in low-resource settings. Feasibility is driven by the support of global calls for inclusive innovation, as evident in the G7 and Organisation for Economic Co-operation and Development (OECD) frameworks (Government of Italy 2024; OECD 2019).

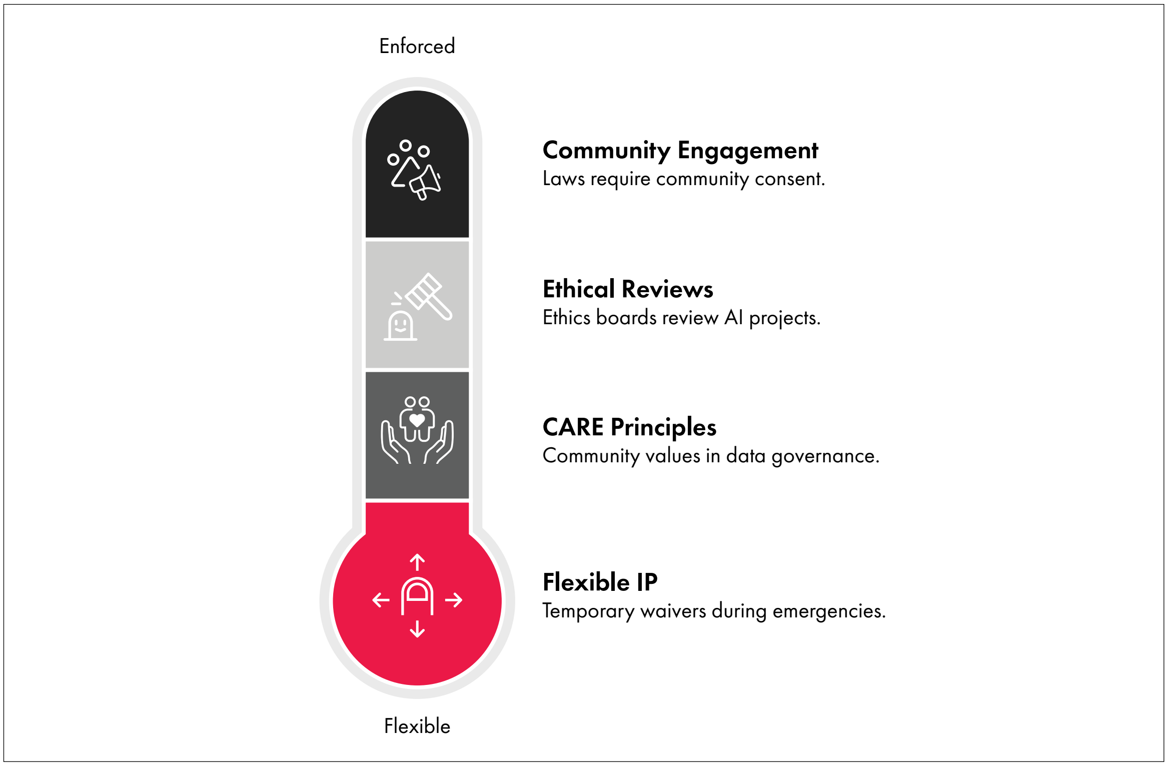
## Policy Recommendations

Figure 2 illustrates the range of policy levers available for ethical AI governance in health care, moving from flexible mechanisms (such as temporary IP waivers) to fully enforced regulatory requirements (such as mandated community engagement). Together, these layers form a continuum of accountability that can be supported by a FAIR/FHIR-based community protocol designed to operationalize each level.

→ **Implement flexible IP mechanisms for crises:** Governments, in collaboration with WIPO, should develop policies that enable temporary IP waivers or compulsory licensing for AI technologies during public health emergencies

(Gurgula and Hull 2021). The authors' proposed protocol embeds these principles by design — supporting dynamic IP licensing models (for instance, open-source, rapid-use waivers, public-interest clauses) that are activated during emergencies, ensuring timely deployment of AI tools. Inspired by discussions on COVID-19 vaccine waivers, this approach enables rapid access to critical tools, such as diagnostic algorithms, particularly in low-resource settings (WTO 2020, 2021). For example, open-source models such as COVID-Net enabled global collaboration during the pandemic (Wang, Lin and Wong 2020). The data collective that manages IP rights can build upon this model, taking into account patents, data and related rights and providing access to the information accordingly. Supported by agreed-upon flexible terms in times of crisis, this mechanism could track and assess health outcomes/impacts, such as reduced mortality rates. This mechanism could be built upon existing precedents, such as C-TAP, which is supported by transparent and inclusive international licensing laws, thereby ensuring its implementation (Pinheiro Alves da Silva and Siqueira Rapini 2022; WHO 2023).

Figure 2: Spectrum of AI Governance Policies: From Flexible to Enforced



*Note:* CARE stands for collective benefit, authority to control, responsibility and ethics.

*Source:* Created by Abbas Yazdinejad.

→ **Adopt the CARE principles for data governance:** National health agencies should mandate the integration of the CARE principles into data governance frameworks for AI projects involving Indigenous or marginalized community data. Generally, the CARE principles complement the FAIR principles for data management, ensuring that data is findable, accessible, interoperable and reusable (Carroll et al. 2021). The CARE principles for Indigenous data governance provide a framework to ensure that data use aligns with community values and ethics. IP rights management would ensure FAIR and CARE principles are met, utilizing a data collective that accounts for various factors such as Indigenous or marginalized community data, authority to control and other vital information about IP rights. Together, these principles empower community-led governance structures to protect rights and foster trust. Measurement would be through monitoring the number of AI projects establishing community-led governance bodies and evaluating community satisfaction through surveys. The proposed community protocol operationalizes these principles by embedding both FAIR and CARE requirements at the metadata, licensing and community consent levels. Feasibility would be supported through global frameworks such as the UN Declaration on the Rights of Indigenous Peoples and pilot programs in Canada, which illustrate practical application.

→ **Establish ethical reviews for AI in health care:** Governments and health regulators should establish independent ethics boards to review all AI projects in health care, using criteria based on the WHO's ethical principles (Perehudoff and Sellin 2020; WHO 2023). These reviews should assess biases, privacy risks and equitable distribution of benefits, ensuring fairness. The community-centred protocol can provide standard templates, consent architectures and audit trails to support these ethical reviews, ensuring consistency and compliance across jurisdictions. Measurement would be through evaluating the percentage of AI projects passing ethical review and the frequency of reported bias-related issues. Feasibility would involve adapting existing medical ethics boards, as seen in frameworks such as the European Union's AI Act, making implementation straightforward.

→ **Enforce community engagement and consent processes:** National legislations should enact laws requiring AI developers to engage with affected communities and obtain informed consent for the use of sensitive health data, particularly when they involve AI systems. This aligns AI solutions with community needs, as demonstrated by Indigenous-led health initiatives during the COVID-19 pandemic (Khan, Galea and Mendez 2025). The protocol includes built-in support for consent management, community oversight dashboards and participatory governance features that enable transparent engagement and accountability. It can be tailored to uphold Indigenous data sovereignty and co-governance models. The data collective can integrate such features into managed access to IP, which will overcome obstacles that would typically take unprecedented amounts of time to access important information for health-care development. Measurement would involve documenting the number of projects with formal engagement processes and measuring community trust through surveys. Feasibility would build on existing medical research consent protocols, ensuring practical adoption.

## Conclusion

Addressing rigid IP frameworks and inadequate data sovereignty is critical to fostering an ethical and equitable AI ecosystem in health care. By implementing flexible IP policies, adopting the CARE principles, mandating ethical reviews and embedding community engagement, policy makers can ensure AI innovations are accessible and trustworthy. At the centre of this transformation is the need for a community-centred protocol — anchored in FAIR and FHIR standards — that enables interoperable, secure and ethically governed AI development. By embedding dynamic IP governance and supporting data sovereignty, such a protocol provides the foundational infrastructure for AI as a public good. International cooperation, as emphasized by the G7 and OECD, is crucial for harmonizing regulations and sharing best practices, thereby preventing digital divides and promoting global health equity. As AI technology evolves, medical practices such as improved diagnostics and recommendations for increased cancer screenings are already emerging in the medical landscape. IP rights management ensures that inventions related to AI health-care innovations will be used lawfully and thus enhance public benefit through greater access to such IP. A data collective that manages this access to IP can ensure that data is not misappropriated, which may hinder research and technological advancement in health care, especially within disadvantaged communities. However, these benefits must not come at the expense of justice and inclusion. Urgent action is needed to reform governance frameworks by embedding participatory models, interoperable standards and rights-based data architectures to ensure AI serves all communities — equitably, transparently and ethically.

# Acronyms and Abbreviations

| | |
|---|---|
| AI | artificial intelligence |
| C-TAP | COVID-19 Technology Access Pool |
| CARE | Collective Benefit, Authority to Control, Responsibility and Ethics |
| CHIME | COVID-19 Health Inequalities Monitoring in England |
| FAIR | Findable, Accessible, Interoperable and Reusable |
| FHIR | Fast Healthcare Interoperability Resources |
| G7 | Group of Seven |
| IP | intellectual property |
| OECD | Organisation for Economic Co-operation and Development |
| PPP | public-private partnership |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organization |

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