

Comments on the Draft National Health Research Policy 2026

July 2026

This is an independent and non-commissioned submission by the Vidhi Centre for Legal Policy, an independent think-tank doing legal research to help make better laws.

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Introduction

On 6 July 2026, the Department of Health Research released a draft of the National Health Research Policy 2026 ('**Draft Policy**') and invited public comments on the same. The Vidhi Centre for Legal Policy ('**Vidhi**') is submitting this Note in response to this call.

Overview of the Draft Policy

The Draft Policy is structured across seven chapters and eight annexures, moving from vision and governance through to agenda-setting, enabling systems, standards, translation, and assessment. Chapter 1 lays out the Policy's purpose, vision, commitments, and scope. Chapter 2 sets up a three-tier governance architecture, which includes the proposed National Health Research Stewardship Committee, the Department of Health Research as the nodal department, and the Indian Council for Medical Research (ICMR) providing scientific and technical leadership. States are expected to align research to local needs. Chapter 3 introduces the National Health Research Agenda as the central instrument for prioritising and coordinating research investment across the country. Chapter 4 addresses the enabling systems needed to translate research into public benefit. Chapter 5 sets ethics, integrity, and data governance standards. Chapter 6 focuses on translating research into policy, clinical practice, and public health action. Chapter 7 establishes a framework for assessing research impact and provides for periodic review of the Policy itself.

This structure signals an effort to move India's health research ecosystem from a fragmented set of institutions and initiatives toward a coordinated and accountable architecture that is rooted in equity.

Promising highlights of the Draft Policy

The Draft Policy exhaustively traces challenges and bottlenecks in the current health research ecosystem – from sparse funding to a systemic shortsightedness regarding what is considered to be of 'value' within the research pipeline. It then establishes the National Research Stewardship Committee, emphasises the necessity for holistically developing national research priorities and the National Research Agenda ('**Agenda**'), and urges the overhaul of the research ecosystem to be representative, inclusive, and responsive.

Certain commendable aspects of the Draft Policy include the following:

Recognition of work across sectors, and convergence of multiple systems of care

- While designing the National Health Research Agenda, priorities that require "work across departments, sectors, disciplines, or systems of care" and "collaboration across institutions and stakeholders" should be actively considered. (*Clause 3.1.1, point 8*)
- The safety and pharmacovigilance for patients receiving therapies from "more than one system of medicine" is acknowledged as a research priority. (*Clause 3.3.3.6*)

Prioritising transparency

- The methodology for setting the Agenda should be publicly justified. (*Clause 3.2.2*)
- Priority project proposals must list their protocols for data management, data sharing, and ethics arrangements. (*Annexure V*)
- Findings from validation of health technologies shall be made publicly available to "inform procurement, regulatory decisions, and programme inclusion". (*Clause 4.6.4.1*)

Expanding perceptions of research environment, capacity, and assessment

- The assessment of health research should go beyond publications and citations, and include publication-equivalent criteria. (Clause 1.7.4)
- Individual advancement should not be limited to metrics of personal research output, but instead also include administration, project management, ethics review, and research appraisal. (Clause 4.2.4.6)
- Institutions have been urged to facilitate researcher-community engagement and recognise that researchers being able to focus on their research properly is "the primary test of a well-functioning research environment". (Clause 4.4.2.3)

Roadmap to the Note

The Note is divided into two parts:

Part A: Recommendations that relate to health research in general, and

Part B: Recommendations that relate to persons with disabilities ('PwDs') in particular.

Each Part presents two categories of recommendations:

- Broad recommendations:** These are top-level suggestions that require change consistently through the Draft Policy, rather than at any single clause. These address structural and conceptual gaps.
- Specific recommendations:** These are clause-wise suggestions that address particular provisions of the Draft Policy that would benefit from clarification, elaboration, or modification.

Part A. Recommendations relating to health research in general

Broad Recommendations

1. Introducing definitions to delineate the Draft Policy's scope better

For a policy as comprehensive and inter-sectoral as the Draft Policy, it is imperative that terminologies are unambiguous and consistent. Introducing nuanced definitions would reduce compliance burden and ensure that responsibilities are assigned appropriately. For instance, the Department of Health Research may consider defining the following terms with relevant considerations:

Term	Nature of ambiguity	Suggestion and guiding references
"research institution"	Research institutions ('RIs') have been acknowledged as "the primary governance-bearing units of the ecosystem" in the Draft Policy. However, the term has been referenced inconsistently in a variety of contexts: RIs engaging in "health research", RIs engaging in "biomedical and health research", and RIs "including medical colleges". It is also unclear if RIs are intended to cover those that primarily deal with clinical care and research (such as medical colleges) or also include non-medical institutions that foster health research in a limited capacity (such as not-for-profit organisations) and institutions that do not currently host health research but are encouraged to do so by the Draft Policy (such as academic institutions that train healthcare professionals).	<u>Vidhi suggests that the definition be drafted broadly, and focus on the health research activity and not the nature of the site itself.</u> Some definitions of RIs across literature and laws include: • "[an institution] engaged in the conception or creation of new knowledge, products, processes, methods and systems related to any aspect of health, such as factors affecting health and ways of promoting and improving it";¹ • "any entity licensed to conduct health research activities, whether independent or affiliated with universities, medical institutions, or other governmental or private sectors of the state, in accordance with the provisions of this law and its regulations".²
"industry"	Across literature, the healthcare industry is often considered to either primarily refer to hospitals, or include other actors that provide care or manufacture tools and equipment for clinical care (such as pharmaceutical companies). However, the Draft Policy appears to refer to 'industry' as actors <i>beyond</i> startups, institutions, non-profit organisations, and even hospitals. This means that statements containing the	<u>Vidhi suggests that the Draft Policy should list the actors that are considered to be a part of "industry".</u> It appears that the term may refer to pharmaceutical companies, but a plain reading of the text does not offer such clarity.

¹ 'Research and its governance in health research institutions in sub-Saharan African countries: results of a questionnaire-based survey' <<https://pmc.ncbi.nlm.nih.gov/articles/PMC4109359/#sec4-0141076814531751>>

² Law No. (6) of 2025 on Regulating Health Research (Qatar)
<<https://www.customs.gov.qa/English/Legislations/Documents/Executive%20Resolutions/2025/Law%20No.%20%286%29%20of%202025%20Regulating%20Health%20Research.pdf>>

Term	Nature of ambiguity	Suggestion and guiding references
	term are unclear, and do not provide sufficient nuance. For instance, the following statements are ambiguous as the actor is not identified properly: • "The enabling conditions for industry participation in health research shall be strengthened in ways consistent with public purpose, national priorities, and appropriate safeguards." (<i>Clause 4.1.1.6</i>) • "Industry exposure shall be incorporated into doctoral training where appropriate." (<i>Clause 4.2.4.1</i>)	
"research misconduct"	The Draft Policy denounces research misconduct and provides that complaints regarding such misconduct should be investigated appropriately. However, unless the term is defined, it is difficult to identify behaviours and activities that may legitimately be complained against.	<u>Vidhi suggests that the Draft Policy should provide an inclusive definition of 'research misconduct'.</u> The Department of Biotechnology's 'Statement on the handling of allegations of research misconduct'³ lists activities that constitute misconduct. The list should be supplemented by additional clauses that reflect emerging research practices, such as the use of Large Language Models. The definition of the term should also include misconduct on other aspects of research projects (such as project management), given that the Policy treats such aspects to be on par in significance with the research itself.

2. Apportioning responsibilities clearly

The Draft Policy sets up different bodies – such as the National Health Research Stewardship Committee and the National Research Integrity Office – and lists their primary responsibilities. Annexure II also lists the responsibilities of different national departments, councils, and institutions across the health research ecosystem.

However, the Draft Policy fails to identify the responsible body in several instances later, especially in the context of preparing guidance and maintaining departmental oversight. For instance, the following clauses of the Draft Policy do not apportion the relevant responsibility to any department or body:

³ Department of Biotechnology, *Statement on the Handling of Allegations of Research Misconduct* (Government of India) <<https://ipgmer.gov.in/pdf/ResearchOversightCommittee/DBT-Statement-handling-research-misconduct-allegations.pdf>>

Cl. no.	Text	Issue
2.3.1.6	DHR and ICMR, in coordination with relevant funding agencies and competent authorities, shall conduct periodic reviews of institutions and programmes supported under DHR/ICMR mechanisms or participating in national health research programmes to assess research output, capacity development, governance effectiveness, and contribution to the national health research ecosystem. [...] Reviews shall be conducted against published, objective criteria , with an opportunity for institutions to respond, and findings shall be used proportionately and transparently.	It is unclear who would be in charge of preparing and publishing such criteria for review of institutions and programs.
6.2.4	Evidence-based guidelines and recommendations for clinical care and public health programmes shall be developed through transparent, systematic processes that assess the quality of evidence, consider the balance of benefits and harms, account for values and preferences, and evaluate feasibility and resource implications. They shall be reviewed at intervals of three to five years, or earlier where significant new evidence emerges. The responsible guideline body shall monitor the evidence base and document the rationale for any decision to update or reaffirm existing recommendations.	It is unclear who the "responsible guideline body" is.
6.3.4	The health technology assessment function shall be supported by a network of regional and institutional resource centres with the capacity to conduct assessments across diverse settings and health domains. A national coordinating mechanism shall maintain standards, support capacity-building, and coordinate priority-setting across the network.	It is unclear who is responsible for designing and operationalising the "national coordinating mechanism".

Vidhi suggests clarifying the apportionment of responsibilities in the clauses listed above, as well as similar provisions throughout the Draft Policy.

3. Bringing States to the foreground of the research ecosystem

With health being a state subject, and in line with the national objective of cooperative federalism, it is imperative that the Policy is designed on the basis of Centre-State coordination and collaboration. The National Health Policy 2017, for instance, illustrates the significance of Centre-State relations for shaping Indian health systems holistically. For instance, it underscores the importance of designing a suitable distribution of responsibility and accountability between the Centre and the States.⁴ The Draft Policy should build Centre-State relations further by accounting for feedback loops between the central and state governments, as well as acknowledging the diverse needs of the research infrastructure of different states while setting the Agenda.

The Draft Policy does commendably account for state autonomy to establish and build their respective research infrastructure, as delineated in Annexure III. It lists certain state obligations to share state-level research development with the national bodies for designing the Agenda, and it urges the

⁴ National Health Policy 2017 (Ministry of Health and Family Welfare, Government of India) p. 34
<<https://nhsrcindia.org/sites/default/files/2021-07/National%20Health%20Policy%202017%20%28English%29%20.pdf>>

Central government to extend technical guidance to states for developing dedicated research financing mechanisms. This further illustrates the back-and-forth collaboration between central and state governments to further research priorities of the country. However, this is not enough to accommodate states' role in shaping the health research ecosystem.

A major limitation to the development of the Agenda is the conspicuous lack of acknowledgement of the responsibility of the central departments and national bodies to include states in the development of national research priorities and Agenda, except for a few references in the Draft Policy. While the Policy substantially acknowledges institution-level contribution to the Agenda and representation to the Stewardship Committee, equivalent provisions for state governments has been relegated to Annexure III. As a result, several strategies in the Draft Policy appear to be inadequately explored. For instance, clause 2.3.3.3 of the Draft Policy should have included advisory and review mechanisms at the state-level as well, instead of limiting it to national and institutional levels.⁵

Vidhi suggests the states should be acknowledged, wherever necessary, throughout the Draft Policy, instead of limiting state-level planning, review, and contributions largely to the Annexures.

⁵ "Advisory and review mechanisms at national and institutional levels shall work in a complementary manner, with appropriate coordination and role clarity."

Specific Recommendations

Sl. no.	Clause no.	Topic	Issues and Recommendations
1.	1.7.4	ICMR-IRIS shall be adopted for assessing research impact.	<u>The Draft Policy should advocate for the ICMR-IRIS to be adjusted for different career stages.</u> For instance, early-career researchers may lack patents to their name, but instead may have recorded more case studies or narrative reviews.⁶ Publication-equivalent assessment should be cognisant of such differences. <u>Additionally, the research assessment criteria must ensure that different types of research outcomes are proportionately marked.</u> For instance, ICMR-IRIS grants ten publication-equivalents to research that has led to policy changes at the national and even international levels, but twenty publication-equivalents to commercialised health technologies being used at scale.⁷ It may not be appropriate to assign higher points to individual commercialised technologies and fewer points to research that is helping shape the entire country's health ecosystem.⁸
2.	3.3.1.5	Across the domains of research identified for the Agenda, the full spectrum from prevention and early detection to treatment, rehabilitation, and long-term care shall be addressed.	<u>This clause in the Draft Policy must include equivalent aspects for non-communicable diseases as well.</u> For instance, morbidity and risk factor surveillance, development of updated nutrition profiles, promotion of safe health-seeking behaviour, identification of cross-sectoral health concerns (effects of climate change and urban planning on health), should also be identified within the spectrum of domains of research.
3.	4.2.	Specific communities within the health research workforce are acknowledged as	<u>The Draft Policy must acknowledge undergraduate and postgraduate students as essential to the complete research enterprise.</u> This is evidenced by the National Medical Commission announcing its plan to

⁶ Sarman Singh, 'Publication-Equivalence: Conceptually Sound but Practically Challenging' (2025) 162(3) Indian J Med Res 423 <<https://pmc.ncbi.nlm.nih.gov/articles/PMC12744535/>>

⁷ Rajiv Bahl, 'Publication-Equivalent as the New Single Currency of Research Impact: The ICMR-Impact of Research and Innovation Scale (ICMR-IRIS)' (2025) 162(2) Indian J Med Res 135 <<https://pmc.ncbi.nlm.nih.gov/articles/PMC12624715/>>

⁸ Siddhesh Zadey, 'While Good, ICMR Impact Scale May Deter Research in Public Interest' *The Hindu* (20 September 2025) <<https://www.thehindu.com/sci-tech/science/icmr-irs-research-impact-evaluation-standards-deter-science-public-interest/article70060783.ece>>

Sl. no.	Clause no.	Topic	Issues and Recommendations
		important actors in the health research ecosystem.	introduce clinical research in the medical education curriculum. ⁹
4.	4.3.3.4 and 5.4.5	Financing instruments shall be designed to share risk between public and private partners while safeguarding public purpose.	<u>The Draft Policy should note that research integrity includes ensuring that pharmaceutical companies as funders must not impede the publication of the otherwise well-founded research on their products or technologies.</u>
5.	4.5.1.2	Interdisciplinary and multisectoral collaborations shall be promoted among government agencies, academic institutions, non-governmental organisations, and other relevant partners.	<u>The Draft Policy may assign a national body or department the responsibility for developing model university-industry research partnership agreements.</u> For instance, the Anusandhan National Research Foundation may be assigned to develop guidance or model agreements as part of its mandate. ¹⁰
6.	5.3.2	Proportionate action would be imposed when research misconduct is substantiated.	<u>Illustrations of 'proportionate action' may be provided in the Draft Policy.</u> For instance, the Department of Biotechnology, in its 'Statement on the handling of allegations of research misconduct' ¹¹ lists the following as actions that may be undertaken in case research misconduct is detected: • A letter of reprimand. • The withdrawal of funding. • Requiring the withdrawal or correction of pending or published abstracts and papers emanating from the research in question. • Changes to the staffing of the particular project. • Special monitoring of future work. • Barring of the grant holder from applying for

⁹ 'NMC Approves Integration of Clinical Research into Medical Curriculum, Assessment and Training, Says Chairperson' *The Times of India* (6 January 2026) <<https://timesofindia.indiatimes.com/education/news/nmc-approves-integration-of-clinical-research-into-medical-curriculum-assessment-and-training-says-chairperson/articleshow/126371540.cms>>

¹⁰ Vidhi Centre for Legal Policy, 'Implement India: 15 Reform Roadmaps for 2025' p. 20 (2025) <<https://vidhilegalpolicy.in/wp-content/uploads/2025/05/Implement-India-2.pdf>>

¹¹ Department of Biotechnology, *Statement on the Handling of Allegations of Research Misconduct* (Government of India) <<https://ipgmer.gov.in/pdf/ResearchOversightCommittee/DBT-Statement-handling-research-misconduct-allegations.pdf>>

Sl. no.	Clause no.	Topic	Issues and Recommendations
			DBT funds for a given period. • Repayment of grant plus interest at the DBT's discretion. • Discussion with the host organisation on its implementation of appropriate administrative disciplinary procedures. <u>Alternatively, it may be clarified who would be responsible for determining the proportionality of the action.</u> For instance, the ICMR may be given the responsibility to develop guidance for determining the proportionality of disciplinary or other actions that may be taken after research misconduct is confirmed.
8.	5.6.2.	When health research data is used to develop artificial intelligence and other computational and data-intensive tools, consent processes shall clearly communicate anticipated uses, and provide for participant choice.	<u>The Draft Policy must provide guidance for determining the range of 'anticipated uses' that should be disclosed while asking for user consent.</u> Additionally, the use of personal data for the purposes of developing artificial intelligence technologies, or any other data-intensive tools, must be subject to the Digital Personal Data Protection Act, 2023 and subordinate legislation under it. <u>All stakeholders covered under this Policy may accordingly be required to develop frameworks for implementation of the provisions of the DPDP Act, 2023, including with respect to arrangements with other parties.</u>
9.	5.6.4	When data is derived from indigenous communities, research shall include benefit-sharing provisions.	<u>The Draft Policy must provide more details about the scope of benefit-sharing, and underscore that research protocols must include arrangements for benefit-sharing.</u> For instance, requirements for priority project proposals listed in Annexure V must include protocols for benefit-sharing among research subjects (individuals or communities) and local researchers. The Draft Policy should also acknowledge the necessity for Ethics Committees and Review Boards to be trained to determine the appropriateness of the proposed benefit-sharing arrangements.¹²
10.	5.6.5	Research with dual-use potential shall be subject	<u>The Draft Policy should identify the appropriate body to oversee such research.</u> The identified body must be

¹² Raffaella Ravinetto and Kris Dierickx, 'Benefit Sharing in the Revised Indian National Ethical Guidelines for Biomedical and Health Research Involving Human Participants' (2018) Indian Journal of Medical Ethics <<https://ijme.in/articles/benefit-sharing-in-the-revised-indian-national-ethical-guidelines-for-biomedical-and-health-research-involving-human-participants/?galley=print>>

Sl. no.	Clause no.	Topic	Issues and Recommendations
		to appropriate oversight.	expressly assigned the responsibility of developing guidance to identify how such dual-use risks be mitigated, and what the role of publishers and editors may be when receiving manuscripts for such research. ¹³
11.	Annexure V	One of the required details in a priority project proposal is protocols related to data management, data sharing, and ethics arrangement.	<u>The Draft Policy must extend this requirement of data management and sharing protocols to all project proposals relating to health-related data, across research institutions.</u> In addition to this, <u>an additional requirement may be created for all project proposals (and not just priority projects) to develop 'Health Data Management Policies', which may address the key legal and compliance considerations that may arise for all covered institutions under the DPDP Act, 2023.</u>

¹³ World Health Organization, 'Global guidance framework for the responsible use of the life sciences: Mitigating biorisks and governing dual-use research' (2022)
<<https://iris.who.int/items/70c8c573-e6a0-4abc-8406-b179e1e24b1c>>

Part B. Recommendations relating to persons with disabilities

Broad Recommendations

While the Draft Policy reflects a broader commitment to equity and inclusion in health research, this perspective is not yet consistently applied to PwDs across its provisions. The recommendations that follow are intended to strengthen this alignment, drawing on India's existing disability rights framework under the Rights of Persons with Disabilities Act, 2016 ('RPwD Act') and its Rules, as well as India's obligations under the United Nations Convention on the Rights of Persons with Disabilities ('UNCRPD').

1. Centering accessibility standards and persons with disabilities throughout the Draft Policy

The Draft Policy names disability explicitly in two places, once, as a research domain demanding increased attention (Clause 3.3.1.4), and under “additional safeguards” during ethics review, alongside other populations in situations of vulnerability. Elsewhere, the Policy uses broader language such as “vulnerable and underserved populations/equity/inclusive/last-mile relevance.” While these terms may be read to encompass PwDs, they do not identify this group specifically. The Policy may benefit from clear identification of PwDs as defined under the RPwD Act, as a group in each section.

2. Addressing Disability Accessibility Across Equity, Technology, Infrastructure, and Governance Provisions

The Draft Policy, on translating research into benefits, presents an opportunity for stronger disability inclusion. Chapter 6's main equity provision (Cl. 6.5: “research shall not be regarded as fully translated unless its benefits reach... groups at elevated risk of exclusion or harm”) does not name disability among these groups, and its list of translation barriers (like, workforce availability, supply chains, infrastructure, geospatial accessibility) does not address physical or communication accessibility, yet, both are relevant to whether PwDs can access translated interventions. The Health Technology Assessment criteria do not ask whether a device or tool can be used independently by a person with a visual or hearing impairment, or with limited manual dexterity. Draft Policy sets no accessibility requirement for research spaces like labs, trial sites, or sample collection centres, even though many sit inside hospitals already legally bound to be accessible under section 40 of the RPwD Act and Rule 15(1)(g).

3. Aligning the Consent and Legal Capacity Framework for Research Participants with Disabilities with the Rights-Based Model

Assumptions about capacity to consent have historically served as grounds for excluding certain populations from health research altogether, rather than as a basis for adapting how consent is sought. The Draft Policy's consent provisions already move toward autonomy, plain language, and adapting to participant vulnerability (Cl. 5.2.8). There is an opportunity to anchor these provisions in the RPwD Act's supported decision-making model, under which a person is assisted to exercise their own legal capacity rather than having decisions made on their behalf. This departs from a substituted-decision or guardianship model of legal capacity, rooted in a binary of full or no capacity, and instead shifts to a spectrum of decision-making support. While most directly relevant to persons with intellectual and developmental disabilities, this shift is equally useful in framing consent for other groups the Draft Policy already recognises as needing additional safeguards, such as children and persons in situations of vulnerability more broadly. For instance, since a participant's support needs, or supporting persons,

may change over time, re-consent processes should be designed to ensure that consent continues to reflect a participant's actual will and preference as their circumstances evolve.

Specific Recommendations

Sl. no.	Clause no.	Topic	Issues and Recommendations
1.	1.4(1); 1.5.1(1); Annexure I	Draft Policy's core commitments and guiding principles establish public purpose and equity as central objectives of health research.	Issue: Cl. 1.4(1) and Cl. 1.5.1(1) identify “underserved populations, regions, institutions, and voices” as the intended beneficiaries of equity-driven research, but do not mention PwDs specifically. The Draft Policy elsewhere relies on broader terms such as “vulnerable and underserved populations/equity/inclusive/last-mile relevance” without naming PwDs as a group. Disability is named explicitly only twice in the entire Draft Policy (Cl. 3.3.1.4 and Cl. 5.2.6(5)); elsewhere it is left to be read into general equity language. Recommendation: <u>Cl. 1.4(1) and Cl. 1.5.1(1), and equivalent equity/inclusion language used elsewhere in the Draft Policy, may be updated to explicitly name “PwDs” as a specific group, in line with RPwD Act s.3(1)-(2), which requires the government to ensure equality and dignity by creating a suitable environment for PwDs, and with UNCRPD Art. 3’s general principles of non-discrimination, full participation, and equality of opportunity. Making this identification clear at the level of core commitments and guiding principles would help ensure that wherever the Policy speaks of equity or inclusion generally, disability is understood to be included as a matter of course, rather than left to inference.</u>
2.	3.2.5	Public and patient participation is recognised as a mechanism for setting research priorities under the Draft Policy.	Issue: Mechanisms for public and patient participation in priority-setting, such as consultations, patient and community advisory panels, and open submissions, do not have to be offered in accessible formats or timelines. Recommendation: <u>Cl. 3.2.5 may be revised to require that participation mechanisms be provided in accessible formats, including Easy Read or plain language, sign language interpretation, accessible digital submission portals, and extended timelines or support when necessary. It should also involve structured consultations with DPOs, in line with UNCRPD Art. 4(3), Art. 9 on accessibility and Art. 21 on freedom of expression and access to information through accessible means, as well as section 42, RPwD Act, which covers access to information and communication technology.</u>

Sl. no.	Clause no.	Topic	Issues and Recommendations
3.	3.3.1.4	Disability and rehabilitation continues to be an under-attended research domain across the Draft Policy.	Issue: “Disability and rehabilitation” is mentioned as a research area that needs more attention, but it is left undefined without any specific sub-priorities. This contrasts with the detailed ten-point treatment of One Health in the same chapter (cl. 3.3.3.4). Recommendation: <u>Cl. 3.3.1.4 could include sub-priorities</u> such as: early identification and screening (RPwD Act s.25(2)(c)); habilitation and rehabilitation science (RPwD Act s.27, s.28; UNCRPD Art.26); assistive technology and rehabilitation engineering (RPwD Act s.28; UNCRPD Art.4(g)); research on intellectual and developmental disabilities related to functioning assessment and certification processes.
4.	5.2.8	Consent processes are required to be adapted to the vulnerability of research participants under the Draft Policy.	Issue: Consent processes need to be adjusted to consider the vulnerabilities of participants. However, there is no requirement for accessible consent formats, such as Easy Read or plain language, visual aids, sign-language interpretation, Braille, tactile formats, stepwise explanations or augmentative and alternative communication for those with sensory, intellectual, or communication disabilities. Recommendation: <u>Cl. 5.2.8 could be changed to require accessible consent formats by default.</u> This would be in line with UNCRPD Art. 21, which addresses the right to seek, receive, and share information through accessible means, and Art. 9, which focuses on accessibility. <u>Cl. 5.2.8 could also be amended in line with the RPwD Act's supported decision-making model,</u> and re-consent processes for longitudinal and data-reuse research should account for changes in a participant's support arrangement over time.

Sl. no.	Clause no.	Topic	Issues and Recommendations
5.	5.2.6(5)	Additional safeguards during ethics review are required for participants in situations of vulnerability, including persons with cognitive or intellectual disabilities, under the Draft Policy.	Issue: As previously stated, this is one of only two places in the Policy that names disability directly. Persons with “cognitive or intellectual disabilities” are listed among the groups needing “additional safeguards” during ethics review. The clause however can benefit from a broad reference to inclusion of PwDs in line with RPwD Act. The clause also does not specify what these safeguards should cover, leaving it open to interpretation, for instance, legal capacity, supported decision-making, or the role of guardians/family members in consent. Recommendations: i) <u>Cl. 5.2.6(5) could be revised to include PwDs in line with the RPwD Act.</u> It should also require that safeguards connect to supported decision-making arrangements that follow RPwD Act s.13, which focuses on “autonomy, dignity, and privacy,” and s.14, which limits guardianship to situations where a court finds it necessary. This would avoid relying on guardian or family proxy consent. This aligns with the domestic implementation of UNCRPD Art.12, which emphasizes equal recognition before the law. ii) Furthermore, <u>National ethical guidance on research that involves people with disabilities, issued by DHR/ICMR under Cl. 5.2.2, should be created in consultation with DPOs, as stated in UNCRPD Art.4(3).</u>
6.	4.1; 6.3; 6.5; 6.6.2	Standards for research infrastructure, technology assessment, and equity are set out under the Draft Policy, but accessibility for persons with disabilities is not consistently built into them.	Issue: Accessibility for PwDs is inconsistent across the Policy's infrastructure, technology assessment, and equity provisions. Cl. 4.1 sets no accessibility standard for research facilities. Cl. 6.3's Health Technology Assessment criteria including, comparative clinical effectiveness, cost-effectiveness, equity implications, do not ask whether a diagnostic device or digital health tool can be used independently by a person with a visual or hearing impairment, or limited manual dexterity. Recommendation: <u>Cl. 4.1 may be changed to require new and upgraded research infrastructure to meet the accessibility standards under RPwD Act s.40 and Rule 15(1)(a) of the RPwD Rules.</u> Further, where such facilities are located within healthcare institutions, the barrier-free access requirements under s.25(1)(b) should be met. <u>In addition, Cl. 6.3 may be changed to add “accessibility and usability for PwDs” as a clear HTA assessment criterion,</u> drawing on Rule 15(1)(g), RPwD Rules.