National Law School of India University
Bengaluru

Centre for Health Law, Policy and Ethics (CHLPE)

Comments on the Draft National Health Research Policy, 2026

Submitted to the Department of Health Research,
Ministry of Health and Family Welfare, Government of India

Submitted by

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27 July 2026

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Comments on the Draft National Health Research Policy, 2026[1]

Submitted to the Department of Health Research, Ministry of Health and Family Welfare, in response to its public comment invitation on the Draft National Health Research Policy, 2026.

These comments cover Chapter 2 (Governance of the National Health Research Ecosystem), Chapter 5 (Ethics, Integrity and Quality Standards), and Chapter 6 (Translation, Application and Public Benefit). No comment is offered on the Policy's scientific priorities, funding, or assessment framework as other stakeholders are better placed to address those. Every legal provision cited below has been checked against its current text. Where a provision could not be fully verified, or a cited Rule is not yet in force, this is stated directly.

General observations

The draft Policy uses aspirational and advisory language. This fits its stated role as a policy document. Paragraph 1.8.5 confirms it "does not replace the mandates or statutory responsibilities of existing authorities." Its real effect depends on two things - (i) how its commitments become binding rules, and how well it aligns with the law that already governs the fields this Policy touches upon. The comments below point to several places where the Policy's text does not track that law closely enough. Sometimes it omits a cross-reference that would resolve ambiguity. Sometimes it proposes something the existing Rules do not currently allow.

One pattern recurs across the Policy. Several provisions create a review or oversight power without a stated appeal or challenge mechanism. This is true of the National

[1] The authors thank Jay Shah, III LL.B. (Hons.), NLSIU, for research assistance in the preparation of this submission.

Research Integrity Office's findings, at paragraph 2.2.2. It is true of institutional performance reviews that feed into resource allocation, at paragraph 2.3.1.6. It is true of the review of an institution's rationale for not adopting a health technology assessment recommendation, at paragraph 6.3.5. This is noted once, as a structural point, rather than as three separate comments. A single due process standard, covering notice, timeline, and a right of response, would resolve all three at once.

Comments on Chapter 2: Governance of the National Health Research Ecosystem

2.1 Two ethics committees for two types of research

> *New Drugs and Clinical Trials Rules, 2019, Rule 2(o): "Ethics Committee" means, for the purpose of — (i) clinical trial, Ethics Committee constituted under rule 7 and registered under rule 8; (ii) biomedical and health research, Ethics Committee constituted under rule 16 and registered under rule 17.*

Paragraph 2.2.1.1 refers to "biomedical and health research" conducted under ICMR's national ethical guidelines, and to "the institutional ethics committee" in the singular. Paragraph 2.2.1.2 separately covers ethics committees reviewing clinical trials for drug approval. Neither paragraph acknowledges that the New Drugs and Clinical Trials Rules, 2019 already create two separate ethics committee regimes. Rules 7 - 8 govern clinical trials and BA/BE studies, registered with the CDSCO. Rules 16 - 17 govern non-trial biomedical and health research, registered with a DHR-designated authority. These are different committees, differently constituted and differently registered. An institution running both kinds of research, for example, a medical college and its teaching hospital, must maintain both, or run two parallel processes through the same body. The Policy commits to "ease of doing research" at paragraph 1.4.4. This split should be acknowledged directly.

Aspect	Ethics Committee for Clinical Trials / BA-BE Studies	Ethics Committee for Biomedical & Health Research (Non-Trial Research)

Applicable Rules	Rules 7-8, New Drugs and Clinical Trials Rules, 2019	Rules 16-17, New Drugs and Clinical Trials Rules, 2019
Research covered	Clinical trials; bioavailability (BA) and bioequivalence (BE) studies	Biomedical and health research not involving clinical trials
Constitution	Constituted under Rule 7	Constituted under Rule 16
Registration	Registered under Rule 8	Registered under Rule 17
Registering authority	Central Licensing Authority (CDSCO)	Authority designated by the Department of Health Research (DHR)
Initial registration	Valid for 5 years	Provisional for 2 years (Form CT-01 to Form CT-03)
Subsequent registration	Renewable every 5 years	Final registration valid 5 years, renewable
Institutional requirement	Must have a Rule 7-8 registered Ethics Committee	Must have a Rule 16-17 registered Ethics Committee
Appeal mechanism	Appeal to the Central Government under Rule 8(4)	Appeal to the Central Government under Rule 17(5)

Rule 17(5) sets a specific timeline for the non-trial appeal route. An aggrieved applicant has 60 working days to appeal to the Central Government, which must then dispose of the appeal within a further 60 working days. Whether Rule 8(4) sets the same or a different timeline for the clinical trial track has not been confirmed, and is worth checking so the two appeal routes can be compared on equal terms.

Recommendation:

Paragraphs 2.2.1.1 and 2.2.1.2 should name Rules 7-8 and Rules 16-17 explicitly, and the Policy should say whether the Policy plans to harmonise these two registration tracks or run them in parallel.

2.2 Conflict of interest is addressed only for the clinical trial ethics committee

> *New Drugs and Clinical Trials Rules, 2019, Rule 7(10): No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the clinical trial or bioavailability or bioequivalence study protocol being reviewed by it, and all members shall sign a declaration to that effect. Rule 7(11)-(12) provide for voluntary withdrawal and for recording the conflict in the minutes.*

Paragraph 2.2.1.5 says institutions and national bodies "shall establish protocols" for managing conflicts of interest. A protocol like this already exists for Rule 7 ethics committees, in some detail. Rule 16, in full, contains no equivalent provision. Its eleven sub-rules cover constitution, registration, provisional and final registration, renewal, reporting of compositional changes, and appeal to the Central Government, but none address conflicts of interest. Rule 16 instead ties non-trial biomedical and health research to the ICMR Guidelines generally, without a comparable procedural safeguard of its own.

Recommendation:

Paragraph 2.2.1.5 should either extend an explicit conflict-of-interest procedure to Rule 16 ethics committees, matching Rule 7(10)-(12), or confirm that conflict-of-interest management for non-trial research rests on the ICMR Guidelines alone, and state as such.

2.3 The single ethics review proposed for multicentre research conflicts with the geographic restrictions in the Rules

Paragraph 2.2.1.4 proposes that multicentre research "avoid unnecessary duplication across participating sites." This includes "a single ethics review, the approval of which is

accepted across all participating sites, where appropriate." For clinical trials and BA/BE studies, the Rules as written do not allow this.

> *Rule 25(ii): where a clinical trial site does not have its own Ethics Committee, the trial may proceed after approval from another site's Ethics Committee or an independent Ethics Committee, provided that the approving Ethics Committee and the trial site are located within the same city or within a radius of 50 km. Rule 35(ii) applies the same condition to bioavailability/bioequivalence studies, and Rule 49(iii) to registered BA/BE study centres.*

Paragraph 2.2.1.4 cannot work for clinical trial and BA/BE research as written. To implement this as proposed, Rules 25(ii), 35(ii) and 49(iii) would either have to be amended, the paragraph's scope has to be narrowed down to exclude this category of research. Each of these three Rules sets the same geographic condition. It does not let one distant committee cover research spread across the country. A committee in Mumbai could not approve a trial site in Bengaluru. This holds no matter how well constituted or experienced that committee is. The Rules do not allow a genuinely national single-review system of the kind 2.2.1.4 seems to provide for. No such geographic limit applies to non-trial biomedical and health research under Chapter IV.

Recommendation:

Either the single-ethics-review model at 2.2.1.4 should be confined to non-trial biomedical and health research, where no geographic restriction applies, or Rules 25(ii), 35(ii) and 49(iii) should be amended as a part of this reform.

2.4 Research integrity - Registry gap and the National Research Integrity Office's uncertain scope

Paragraph 2.2.2.3 names the Clinical Trials Registry, India (CTRI) as the nodal registration agency for clinical trials. No equivalent registry exists for non-trial biomedical and health research involving human participants. That research is governed only by the ICMR Guidelines. It has no registration requirement of its own.

Paragraph 2.2.2.4 says DHR "may establish" a National Research Integrity Office (NRIO). But paragraph 1.6.1(4) sets integrity and quality as a strategic direction, and paragraph 5.3.2 refers to the NRIO's functions as if it already exists. The term "may" does not align with either framing. Paragraph 2.2.2.5 says the NRIO will not act as a forum of first instance and may decline matters outside its remit. But the draft does not say who sits on the NRIO or how they are appointed. It also does not address overlap with existing bodies. The National Medical Commission already regulates professional conduct for registered doctors. The UGC already regulates academic integrity for university researchers. Both cover much of the same research community the NRIO would oversee. The Policy does not say whether NRIO findings bind these bodies or merely advise them, or how an appeal would work.

Recommendation:

Paragraph 2.2.2.4 should read "shall establish," not "may establish." The Policy should address the registry gap for non-trial research, and clarify the NRIO's jurisdiction relative to the National Medical Commission and UGC, including whether its findings are binding and mandatory or merely advisory.

2.5 No statutory basis specified for animal and genetic research oversight:

Paragraphs 2.2.3.3-2.2.3.5 mention Institutional Animal Ethics Committees (IAECs), the Review Committee on Genetic Manipulation (RCGM), and Institutional Biosafety Committees (IBSCs). None of these paragraphs names the statutes that give these bodies their authority. The relevant statutes are:

The Prevention of Cruelty to Animals Act, 1960, and the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 (amended in 2001 and 2006). Section 15 of the Act lets the Central Government set up a committee to supervise animal experiments. That committee is now called the Committee for Control and Supervision of Experiments on Animals (CCSEA). It was renamed from CPCSEA by government order in January 2023. It operates under the Department of Animal Husbandry and Dairying, Ministry of Fisheries, Animal Husbandry and Dairying. It registers and oversees IAECs.

The Environment (Protection) Act, 1986, and the 1989 Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/Genetically Engineered Organisms or Cells. These Rules govern the RCGM and IBSC, both under the Department of Biotechnology, Ministry of Science and Technology. They also govern the Genetic Engineering Appraisal Committee (GEAC), under the Ministry of Environment, Forest and Climate Change.

Recommendation:

Paragraphs 2.2.3.3-2.2.3.5 should name the Prevention of Cruelty to Animals Act, 1960 and the Environment (Protection) Act, 1986, their Rules, and the CCSEA, RCGM, IBSC and GEAC, as the statutory basis for this oversight.

2.6 International collaboration - applicable law for cross-border transfer of biological materials is not specified

Paragraph 2.2.4.1 requires cross-border transfer of biological materials, and cross-border data agreements, to follow "applicable national regulations and clearance processes." It does not specifically identify them. For biological materials and pathogens, the relevant law is the Environment (Protection) Act, 1986 and its Rules, together with the ICMR's National Ethical Guidelines. These govern the handling of biological material and the data it generates.

Recommendation:

Paragraph 2.2.4.1 should specify the Environment (Protection) Act, 1986 and its Rules, and the applicable ICMR Guidelines, as the governing framework for cross-border transfer of biological materials and pathogens.

2.7 Cross-border data transfer - interaction with the DPDP Act is unaddressed, and the relevant Rules are not yet in force

Paragraphs 2.2.4.2-2.2.4.3 require international collaboration arrangements to pass through the Health Ministry's Screening Committee (HMSC), the Screening Committee

for Research Proposals (SCRP), or the relevant DBT screening committee. These bodies weigh national priorities, biosafety, and data security. The draft does not say how this screening relates to the Digital Personal Data Protection Act, 2023.

> *DPDP Act, 2023, Section 16(1): the Central Government may, by notification, restrict the transfer of personal data by a Data Fiduciary to a notified country or territory. Section 16(2) preserves any Indian law providing a higher degree of protection.*

The Digital Personal Data Protection Rules, 2025 put this into practice. They were notified on 13 November 2025. Rule 15 sets out how cross-border transfer works. Rule 16 gives a conditional exemption for research, archiving, or statistical processing, tied to the Second Schedule standards and Section 17(2)(b) of the Act. Neither Rule is in force yet. The Rules commence in phases - only Rules 1, 2, and 17–21 took effect on notification; Rules 3, 5–16, 22, and 23, which include both the transfer mechanism and the research exemption, come into force 18 months later, around 13 May 2027. So right now, no rule-based transfer restriction or research exemption operates. Only the bare Section 16 power exists, and even that depends on a country-notification the government has not yet issued.

Health data also gets no separate statutory protection under the DPDP framework. The GDPR treats health data as a special category, under Article 9. The DPDP Act does not. It defines “personal data” generically at Section 2(t), with no separate category for health or genomic data.

Recommendation:

The Policy should clarify how HMSC/SCRP/DBT clearance is meant to interact with the DPDP Act’s cross-border transfer regime, note that Rules 15 and 16 of the DPDP Rules, 2025 will not commence until around 13 May 2027, and confirm whether institutional screening will independently satisfy the Act once those Rules take effect.

2.8 Authorship recognition should be tied to the existing ICMJE-based standard

Paragraph 2.2.4.4 requires international collaboration to ensure Indian investigators get "appropriate recognition of intellectual contribution" and co-authorship rights. It does not define the standard. Section 3.5.1 of the ICMR's 2017 Guidelines already does this. It directs researchers to the ICMJE authorship criteria, which include substantial contribution to the work, drafting or revision, final approval, and accountability. It also states that authorship should never be gifted, and ghost authorship is unacceptable.

Recommendation:

Paragraph 2.2.4.4 should cross-reference Section 3.5 of the ICMR 2017 Guidelines, so "appropriate recognition of intellectual contribution" is anchored to an existing, objective standard.

2.9 Institutional oversight bodies are not linked to the ethics committee bifurcation addressed above

Paragraph 2.3.2 lists Institutional Ethics Committees, Institutional Animal Ethics Committees, Institutional Biosafety Committees, and Data and Safety Monitoring Boards (DSMBs) as bodies an institution "may include." This list does not relate to the two-track ethics committee structure outlined in the New Drugs and Clinical Trials Rules, 2019. It's unclear if "Institutional Ethics Committees" refers to both tracks or just one.

No rule within the New Drugs and Clinical Trials Rules, 2019 creates or names a Data and Safety Monitoring Board. CDSCO's own guidance for industry mentions a Data Safety Monitoring Board only in passing, as a field to be completed "as applicable" in a clinical trial status report, which describes a practice that sometimes exists rather than a body the guidance itself constitutes. Internationally, DSMB oversight is addressed through the ICH's E6(R3) Good Clinical Practice guideline and through operational frameworks issued by bodies such as the WHO and the United States National Institutes of Health, none of which carry the force of Indian law. On this basis, Data and Safety Monitoring Boards in India appear to operate as a matter of institutional and sponsor practice, following these international norms, rather than under any Indian statutory requirement, as reflected from a review of the Rules and the CDSCO document identified above.

Recommendation:

Paragraph 2.3.2 should cross-reference the Rule 7-8/Rule 16-17 distinction addressed at 2.1, and should confirm that Data and Safety Monitoring Boards operate as institutional and sponsor practice rather than under statutory requirement, consistent with CDSCO's own guidance, or identify the specific legal basis if one in fact exists.

Comments on Chapter 5 - Ethics, Integrity and Quality Standards

5.1 The list of vulnerable and marginalised populations is narrower than existing ICMR guidance

Paragraph 5.2.6 lists groups needing extra safeguards - children, pregnant women, persons with cognitive or intellectual disabilities, prisoners and persons in detention, economically disadvantaged populations, indigenous and tribal communities, and populations in emergencies or disasters. It leaves out sexual minorities, sex workers, persons with reduced autonomy, terminally ill patients, and persons in hierarchical relationships with an investigator, such as students or employees. Section 6 of the ICMR's 2017 Guidelines covers all of these. The Policy should also cross-reference the National Ethical Guidelines for Biomedical Research Involving Children, 2017, wherever it addresses research involving children.

Recommendation:

Paragraph 5.2.6 should either be expanded to match Section 6 of the ICMR 2017 Guidelines, or state plainly that its list is illustrative and non-exhaustive, subordinate to the ICMR Guidelines. The Policy should separately cross-reference the National Ethical Guidelines for Biomedical Research Involving Children, 2017.

5.2 Expedited review and consent waiver in public health emergencies need a specific anchor

Paragraph 5.2.3 allows expedited ethics review and consent adaptation during public health emergencies, including consent that is deferred or waived, "as determined by the ethics committee in accordance with national ethical guidelines." It does not cite the specific provision. Section 5.7 of the ICMR 2017 Guidelines sets out the actual conditions for a consent waiver, which include scenarios such as the research cannot practicably proceed without it, it is scientifically justified, and it falls into a listed category such as retrospective, de-identified, public-domain, or humanitarian-emergency research. A

general reference to “national ethical guidelines,” without pointing to this section, risks inconsistent decisions by ethics committees across the country.

Separately, the Third Schedule of the New Drugs and Clinical Trials Rules, 2019 requires audio-video recording of informed consent for vulnerable subjects in trials of new chemical or molecular entities. A public health emergency is exactly when new drugs get tested urgently, often on vulnerable populations. The Policy's emergency-research provision should account for this recording requirement. Right now it addresses the consent waiver alone.

Recommendation:

Paragraph 5.2.3 should cite Section 5.7 (and Box 5.2) of the ICMR 2017 Guidelines directly, and cross-reference the Third Schedule audio-video consent-recording requirement for vulnerable trial subjects.

5.3 Post-trial access and community benefit sharing - the Biological Diversity Act does not extend to human-derived material

Paragraphs 5.2.4-5.2.5 require post-trial access for research that produces effective interventions. They also require research that collects data or biological material from communities to return findings and share benefits “in forms that are meaningful to those communities.” India's most developed benefit-sharing law is the Biological Diversity Act, 2002. Under it, the National Biodiversity Authority determines fair and equitable benefit sharing, at Sections 20-21, for access to biological resources. But Section 2(c) of that Act defines “biological resources” to expressly exclude human genetic material. So the Act’s benefit-sharing regime does not cover biological material or data from human research participants. Paragraph 5.2.5’s benefit-sharing language is about communities whose data or biological material was used in research, not about access to biodiversity. Therefore, the Act cannot serve as its legal anchor.

India has no benefit-sharing statute for human-derived research material and data equivalent to the Biological Diversity Act. Where health research does draw on traditional knowledge or non-human biological resources, such as ethnobotanical or

traditional-medicine research, the Biological Diversity Act framework does apply and clearance under Sections 19-21 sought from the National Biodiversity Authority would be the reference point there.

Recommendation:

The Policy should acknowledge that no statutory benefit-sharing mechanism equivalent to the Biological Diversity Act currently covers human-derived biological material and data. It should either develop such a framework or clarify that post-trial access and benefit-sharing under 5.2.4-5.2.5 will run through institutional agreements and consent documentation instead.

5.4 Compensation - the Policy's uniform language obscures a dual-track regime

Paragraph 5.2.6(4) requires "competent recognition, care, referral, support, and compensation" where injury or harm is found to be research-related. It does not distinguish between types of research. For clinical trials and BA/BE studies, Rules 39-42 of the New Drugs and Clinical Trials Rules, 2019 set a mandatory, formula-based compensation mechanism under the Seventh Schedule. The Central Licensing Authority administers it, based on advice from an independent expert committee. Rule 43 works differently. It covers biomedical and health research, the kind overseen by a Rule 16 ethics committee. For this track, compensation follows the ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 instead. The 2017 Guidelines set no formula. They tell the ethics committee to weigh each case on its own facts, reviewing the type of research, how serious the injury was, and lost wages. The Policy's phrase "related to research" treats both tracks as the same when they are not.

Recommendation:

Paragraph 5.2.6(4) should state that compensation for clinical trials and BA/BE studies follows Rules 39-42 and the Seventh Schedule, while compensation for other biomedical

and health research follows Rule 43 and the ICMR Guidelines, and should flag that the latter track has no defined formula.

5.5 Mental illness is a distinct vulnerability from intellectual disability, with its own statutory consent layer

Paragraph 5.2.6(5) lists persons with cognitive or intellectual disabilities among vulnerable groups. It does not separately name persons with mental illness. In Suchita Srivastava v. Chandigarh Administration (2009), the Supreme Court drew on the Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995. It distinguished "mental illness" from "mental retardation" (now called intellectual disability) as two separate forms of disability. The Rights of Persons with Disabilities Act, 2016 retains that distinction. Its Schedule defines intellectual disability and mental illness separately.

This distinction matters under the Mental Healthcare Act, 2017. Section 99 requires free and informed consent from a person with mental illness for any research involving interviews, or psychological, physical, chemical, or medicinal intervention. If the person cannot consent, research may proceed only with permission from the State Mental Health Authority. That permission comes with conditions such as the research cannot be done on persons capable of consenting, it must address the mental health needs of the relevant population, and ethics committee approval must also be in place. Ethics committee approval alone, under Rule 7 or Rule 16 of the New Drugs and Clinical Trials Rules, 2019, is not enough for research involving someone who lacks capacity due to mental illness. The State Authority permission is a separate, non-negotiable statutory requirement. The Policy does not seem to reflect it.

Recommendation:

Mental illness should be added as a distinct vulnerable category at paragraph 5.2.6(5), separate from intellectual disability, and the Policy should note the additional State Mental Health Authority permission required under Section 99 of the Mental Healthcare Act, 2017.

5.6 Consent for persons with disabilities is governed by three inconsistent frameworks

Three separate regimes govern consent for a person with disability, for research and for data purposes, which the Policy does not reconcile. The ICMR 2017 Guidelines, at Section 2.2.1, allow consent from a "Legally Acceptable/Authorised Representative" where the participant cannot consent. Section 14 of the Rights of Persons with Disabilities Act, 2016 uses a different model of limited guardianship. A District Court or notified authority appoints the guardian, who exercises decisions jointly with the person, based on mutual trust. This is materially different from an LAR simply consenting on the person's behalf.

A third framework governs data processing specifically. Rule 11 of the Digital Personal Data Protection Rules, 2025 requires a Data Fiduciary to verify that anyone claiming to be a person with disability's "lawful guardian" was actually appointed under the Rights of Persons with Disabilities Act, 2016, or the National Trust Act, 1999, as applicable. Rule 11, like Rule 16 of the DPDP Rules, 2025 discussed at 2.7 above, is not yet in force. It commences around 13 May 2027. Once it does, it will apply alongside the ICMR and RPWD frameworks, not replace them. All three use different terms and different appointing authorities.

Recommendation:

DHR and ICMR should issue harmonising guidance reconciling the ICMR Guidelines Legally Acceptable/Authorised Representative (LAR) model, the RPWD Act's limited guardianship model, and the DPDP Rules' lawful-guardian verification requirement, so institutions are not left to reconcile three inconsistent frameworks on their own.

5.7 "Sensitive data" has no statutory basis under the DPDP framework

Paragraphs 5.5.5 and 5.6.4 refer to "restricted categories of personal data" and call for "specific governance arrangements" for genomic and other "sensitive data types." Whether this has a statutory basis depends on which data protection regime applies. The law currently in force, the Information Technology Act, 2000, read with the Information

Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 (the SPDI Rules), does define "sensitive personal data or information" under Rule 3. That definition covers passwords, financial information, physical, physiological, and mental health condition, sexual orientation, medical records and history, and biometric information. On this basis, health and genomic data are already treated as a distinct, higher-protection category under current law.

However, this will change once the substantive provisions of the Digital Personal Data Protection Act, 2023 and the DPDP Rules, 2025 commence and repeal Section 43A of the IT Act and the SPDI Rules on 13 May 2027. Unlike the SPDI Rules, the DPDP Act adopts a single, broad definition of "personal data" and creates no separate category for sensitive or health data. The only relevant provision in the DPDP framework is the research exemption under Section 17(2)(b) of the Act and Rule 16 of the Rules, which is conditional relief from the Act rather than a heightened-protection category. Therefore, the Policy's references to "sensitive data types" rest on real law today, but that law is scheduled for repeal before the Policy is likely to be implemented. If the Policy wants a distinct, higher-protection tier for genomic or health data to survive that transition, it needs its own statutory backing, since neither the DPDP Act nor its Rules currently provide one.

Recommendation:

The Policy should align its definition of "sensitive data types" with Rule 3 of the SPDI Rules, 2011 while that definition remains in force, and should separately state how, if at all, this protection will be preserved once the SPDI Rules are repealed on 13 May 2027 and the DPDP Act's single personal data definition takes full effect.

5.8 Dual-use research oversight lacks statutory basis

Paragraph 5.6.5 requires "appropriate oversight" of dual-use research. It does not say which institution, or which law, is responsible. India has no dedicated dual-use research statute. Export of biological materials, pathogens, and related equipment is controlled through the Special Chemicals, Organisms, Materials, Equipment and Technologies

(SCOMET) list, administered by the Directorate General of Foreign Trade under the Foreign Trade (Development and Regulation) Act, 1992.

Separately, the Weapons of Mass Destruction and their Delivery Systems (Prohibition of Unlawful Activities) Act, 2005 defines biological weapons, at Section 4(a), as biological agents or toxins of types and quantities that have no justification for prophylactic, protective, or other peaceful purposes, and criminalises their unlawful manufacture, acquisition, possession, development, and transport. Domestically, the RCGM, IBSC, and GEAC, discussed at 2.5 above and all constituted under the 1989 Rules under the Environment (Protection) Act, 1986, work as separate, uncoordinated points of review. None is expressly mandated to screen for dual-use risk.

Recommendation:

The Policy should either designate the RCGM, IBSC and GEAC (or a new body) as responsible for dual-use screening under paragraph 5.6.5, or acknowledge the absence of a dedicated legal framework and commit to developing one.

5.9 AI and computational tools built on health research data have no identified legal anchor

Paragraph 5.6.2 states that the use of health research data to develop artificial intelligence and other computational tools "shall be governed by applicable national guidelines and regulatory frameworks," without naming them. Nothing currently enacted or pending in India addresses this specific use. The Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Amendment Rules, 2026, notified in February 2026, are a binding rule, but they govern AI-generated synthetic content on intermediary platforms and have no bearing on the use of health research data to train models. MeitY's India AI Governance Guidelines, issued in November 2025, set out non-binding principles for responsible AI adoption generally. An Artificial Intelligence (Ethics and Accountability) Bill, 2025 has been introduced as a Private Member's Bill in the Lok Sabha, proposing a statutory ethics committee and mandatory ethical review for high-risk AI systems, but it has not been enacted. The Digital Personal Data Protection

Act, 2023 governs the underlying personal data, but does not address algorithm-specific concerns such as model-training consent, bias, or explainability. Paragraph 5.6.3 separately requires institutions to consider these concerns.

Recommendation:

Paragraph 5.6.2 should name the actual legal basis for AI and computational-tool governance, given that no binding sector-specific regulation currently exists, and DHR/ICMR should be directed to issue guidance on model-training consent specifically, since this is not covered by the existing 2017 Guidelines.

5.10 Undisclosed use of AI tools in research has no clear place in the misconduct framework

Paragraph 5.3.9 requires researchers to disclose the use of artificial intelligence tools in the design, conduct, analysis, or writing of research, and holds them accountable for the integrity, accuracy, and originality of the resulting work. Paragraph 5.3.2, discussed at 2.4 above, defines research misconduct as fabrication, falsification, and plagiarism. It does not list undisclosed AI use as a form of misconduct, or as a questionable research practice distinct from misconduct. Whether a researcher who fails to disclose AI use, as 5.3.9 requires, would fall within the National Research Integrity Office's jurisdiction at all is unclear, since that jurisdiction is anchored to the categories named at 5.3.2.

A related gap concerns authorship. Section 2(d)(vi) of the Copyright Act, 1957 attributes authorship of a computer-generated work to "the person who causes the work to be created," a provision that could in principle extend to AI-assisted research output. But its application to generative AI specifically remains unsettled. The Copyright Office's 2020 decision to register an artwork with an AI tool named as co-author was later withdrawn, with the Office questioning the tool's status as an author under this same provision. Paragraph 5.3.9's disclosure requirement does not address how this unsettled question affects authorship or ownership of research output produced with AI assistance.

Recommendation:

Paragraph 5.3.2 should state explicitly whether undisclosed use of artificial intelligence tools, required to be disclosed under paragraph 5.3.9, is treated as research misconduct or as a questionable research practice, and the Policy should address how AI-assisted contributions affect authorship and ownership of the resulting work, given the unsettled state of Section 2(d)(vi) of the Copyright Act, 1957 on this point.

Comments on Chapter 6: Translation, Application and Public Benefit

6.1 The legal status of the HTAIn function is unclear, and this matters for pricing decisions

Paragraph 6.3.2 requires the research ecosystem to maintain a standing health technology assessment (HTA) function within the governance architecture set out in Chapter 2. It does not say whether this function has a statutory basis.

> *Department of Health Research website: "Government of India has created an institutional arrangement called the Health Technology Assessment in India (HTAIn) under the Department of Health Research (DHR). HTAIn is entrusted with the responsibility to collate and where needed generate evidence related to the clinical effectiveness, cost-effectiveness, and safety of medicines, devices and health programs using the Health Technology Assessment (HTA) approach."*

This reads as an executive or advisory arrangement and not a statutory one. The Policy does not confirm this either way. This matters because paragraph 6.3.5 places a firm demand on other institutions. Bodies responsible for public health programmes, insurance schemes, procurement, and regulation must use HTA evidence in decisions on inclusion, pricing, and scaling. They must "formally integrate" HTA recommendations into their own decision-making. The Policy does not name the nodal body carrying this weight, even as it expects other institutions to treat that body's output as close to binding.

This creates a specific conflict. The National Pharmaceutical Pricing Authority (NPPA) already derives its own pricing powers from the Drugs (Prices Control) Order, 2013, issued under the Essential Commodities Act, 1955. If HTAIn recommendations must be "formally integrated" into NPPA's pricing decisions, the Policy must indicate whether that integration binds NPPA, or whether NPPA keeps independent statutory discretion under the DPCO.

Recommendation:

The Policy should state whether HTAIn will be placed on a statutory footing or remain a non-statutory advisory body under DHR, and should clarify how "formal integration" of HTA recommendations interacts with NPPA's independent statutory pricing power under the Drugs (Prices Control) Order, 2013.

6.2 No authority is identified to review an institution's non-adoption of an HTA recommendation

Paragraph 6.3.5 lets an institution depart from an HTA recommendation if it documents its rationale, by adopting a comply-or-explain model. The Policy does not identify who is responsible for reviewing that rationale, on what standard, or what happens if the rationale is inadequate. HTA evidence is meant to inform national insurance schemes and the procurement of medicines and diagnostics. A weak or unreviewed rationale carries real financial consequences.

Paragraph 2.1.1.4(6) separately gives the National Health Research Stewardship Committee (NHRSC) a function described as "data sharing and translation into policy, practice, and public benefit," enabling data reuse and coordinating the translation of research into practice and policy. This is the closest the Policy comes to naming a body responsible for translation generally. It does not clarify whether the NHRSC itself is meant to review HTA non-adoption decisions, or whether a separate governance body will be responsible.

Recommendation:

The Policy should name the authority responsible for reviewing an institution's stated rationale for not adopting an HTA recommendation, set a standard for that review, and confirm whether the NHRSC or a dedicated body performs this function.

6.3 Chapter 6 addresses evidence and HTA, but not the regulatory pathway

Paragraph 6.3.2 distinguishes HTA from evidence synthesis and clinical guidelines by its focus on comparative effectiveness, cost, and equity,

feeding into procurement, pricing, and benefit-package decisions. Chapter 6 does not separately address a fourth pathway which is research evidence feeding directly into regulatory reform itself, for example, accelerated or conditional drug approvals.

Two provisions elsewhere in the Policy show this pathway already exists in practice. Paragraph 2.2.3 addresses regulatory and safety compliance under the CDSCO/NDCT Rules framework. Paragraph 4.6.2.1 commits to strengthening national regulatory science capacity, so research can meet regulatory requirements and contribute to evidence-based regulatory standards.

> *New Drugs and Clinical Trials Rules, 2019, Rule 101: "Name of countries for purpose of new drug approval. The Central Licencing Authority, with the approval of the Central Government, may specify, by an order, the name of the countries, from time to time, for considering waiver of local clinical trial for approval of new drugs under Chapter X and for grant of permission for conduct of clinical trial under Chapter V."*

Rule 101 shows what this looks like operationally. The Central Licensing Authority can waive the local clinical trial requirement for a new drug already approved in a specified country, on the strength of that country's own regulatory review. This is a concrete, existing example of a research-to-regulation pathway distinct from HTA, evidence synthesis, or clinical guidelines. Chapter 6, as drafted, does not address it.

Recommendation:

Chapter 6 should add a fourth translation pathway, from research evidence to regulatory reform, alongside HTA, evidence synthesis, and clinical guidelines, and should reference paragraph 4.6.2.1 and mechanisms such as the Rule 101 waiver as examples of this pathway already in operation.

6.4 Palliative care is not named as a research or translation priority

Paragraph 3.3.1.2, in Chapter 3, lists the persistent health burdens the National Health Research Agenda is meant to prioritise which include tuberculosis, vector-borne

diseases, antimicrobial resistance, mental health, metabolic and other non-communicable diseases, cancer, anaemia, child malnutrition, women's health, maternal and neonatal mortality, primary health care, and emergency care. Palliative and end-of-life care is not among them.

Chapter 6 does not set its own disease priorities. Its evidence synthesis function, at paragraph 6.2.1, and its health technology assessment function, at paragraph 6.3.2, both operate on whatever the Agenda in Chapter 3 names as a priority. So the gap at 3.3.1.2 carries forward into this chapter and nothing in the evidence synthesis or health technology assessment pathways creates a route for palliative and end-of-life care research to be systematically translated, because it is not identified as a priority area.

Palliative care was recognised as a priority in the National Health Policy, 2017. The rising NCD and cancer burden, already named at 3.3.1.2 as the rationale for those priority areas, applies equally to the need for palliative care research.

Recommendation:

Paragraph 3.3.1.2 should add palliative and end-of-life care as an identified priority, and Chapter 6 should confirm that its evidence synthesis (6.2) and health technology assessment (6.3) pathways will apply to it once identified, the same as for the other listed conditions.

6.5 Equity in translation does not address uneven state-level legal and administrative capacity

Paragraph 6.5.2 lists the structural barriers the Policy's equity provisions are meant to address -health workforce availability and sustainability, supply chain integrity, infrastructure for diagnostics, monitoring, and quality assurance, and geospatial accessibility. Paragraphs 6.5.1 and 6.5.3 add socio-cultural context and local values to this list. None of the three paragraphs mentions legal, regulatory, or administrative capacity.

This matters because paragraph 2.1.3.1, in Chapter 2, already requires States and Union Territories to "strengthen the translation of evidence into local programmes, service delivery, and public health action" within their own jurisdictions. Functioning ethics committees, data protection compliance capacity, and legal advisory capacity within state health departments vary considerably. An equity framework that lists workforce, supply chain, and infrastructure barriers, but not legal and administrative capacity, risks widening, rather than narrowing, the equity gap paragraph 6.5.3 requires translation reviews to assess.

Recommendation:

Paragraph 6.5.2 should add legal and administrative capacity-building at the state level to its list of structural barriers, alongside workforce, supply chain, and infrastructure, consistent with the translation role already assigned to States at paragraph 2.1.3.1.

Summary of recommendations:

Chapter 2:

1. Name Rules 7-8 and 16-17 explicitly at 2.2.1.1-2.2.1.2, and say whether DHR will harmonise the two registration tracks.
2. Extend a conflict-of-interest requirement to Rule 16 ethics committees, or confirm reliance on the ICMR Guidelines alone.
3. Confine the single-ethics-review model at 2.2.1.4 to non-trial research, or amend Rules 25(ii), 35(ii) and 49(iii).
4. Change "may establish to "shall establish" for the NRIO. Fix the non-trial research registry gap. Clarify NRIO's jurisdiction relative to the NMC and UGC.
5. Name the Prevention of Cruelty to Animals Act, 1960 and Environment (Protection) Act, 1986 as the basis for animal and biosafety oversight.
6. Specify the applicable law for cross-border transfer of biological materials at 2.2.4.1.
7. Clarify how HMSC/SCRP/DBT screening interacts with the DPDP Act, and note that Rules 15 and 16 are not yet in force.
8. Cross-reference the ICMJE authorship criteria already in the ICMR 2017 Guidelines at 2.2.4.4.
9. Cross-reference the ethics committee bifurcation at 2.3.2, and state the legal basis for Data and Safety Monitoring Boards.

Chapter 5:

10. Expand the vulnerable-groups list at 5.2.6 to match ICMR Guidelines Section 6, or state it is non-exhaustive. Cross-reference the ICMR paediatric research guidelines.
11. Cite ICMR Guidelines Section 5.7 directly for emergency consent waiver, and cross-reference the Third Schedule audio-video consent requirement.
12. Acknowledge that no benefit-sharing statute covers human-derived research material, rather than relying on the Biological Diversity Act, which excludes it.

13. Clarify the two compensation tracks - the Seventh Schedule formula for trials, and the undefined ICMR Guidelines standard for other research.
14. Add mental illness as a distinct vulnerable category, and note the Mental Healthcare Act Section 99 permission requirement.
15. Commission harmonising guidance across the ICMR, RPWD Act, and DPDP Rules consent-for-disability frameworks.
16. State plainly that "sensitive data types" have no current statutory basis under the DPDP framework.
17. Designate responsibility for dual-use research screening, or acknowledge the gap and propose reform.
18. Name the legal basis for AI and computational-tool governance at 5.6.2, and direct DHR/ICMR to issue guidance on model-training consent.
19. State whether undisclosed AI use, required to be disclosed under 5.3.9, counts as research misconduct under 5.3.2, and address AI-assisted authorship and ownership given the unsettled state of Section 2(d)(vi) of the Copyright Act, 1957.

Chapter 6:

20. State whether HTAIn will be placed on a statutory footing, and clarify how "formal integration" of HTA recommendations interacts with NPPA's independent pricing power under the DPCO, 2013.
21. Name the authority responsible for reviewing an institution's rationale for not adopting an HTA recommendation, and confirm whether the NHRSC performs this role.
22. Add a fourth translation pathway to Chapter 6, research evidence feeding into regulatory reform, alongside HTA, evidence synthesis, and clinical guidelines.
23. Add palliative and end-of-life care as a named research and translation priority.
24. Address state-level legal and administrative capacity as a distinct equity concern in the translation chapter.