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Gender Bias and Misogyny in Medical Research: Law, Ethics, and Reform

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ABSTRACT

The systematic underrepresentation of women in clinical trials and biomedical research represents a long-standing breach of the principles of scientific integrity, medical ethics, and social justice. Despite regulatory requirements introduced since the NIH Revitalization Act of 1993 in the United States, and comparable ethical principles elsewhere, women constitute only 41.2 percent of clinical-trial participants although they make up roughly half of the patient population. This imbalance has produced what researchers describe as the gender data gap, a serious deficit of evidence on the effects of pharmaceutical interventions and medical devices on women as compared with men. This paper analyses the legal, ethical, and institutional processes that contribute to gender bias in medical research, with particular attention to the Indian regulatory environment. By contrasting international legal systems with Indian policy instruments, this study addresses current systemic gaps in research and proposes detailed mechanisms of reform. Its central thesis is that gender bias must be tackled through the coordinated operation of legal change, institutional accountability, and intersectional feminist perspectives on research ethics. Specific recommendations include compulsory reporting of sex-disaggregated data in clinical trials, strengthened enforcement within the Indian regulatory framework (especially the CDSCO and ICMR systems), and the integration of gender medicine into medical-education programmes.

Keywords: *Gender bias, clinical trials, medical research ethics, pharmaceutical regulation, India, women's health.*

I. INTRODUCTION

The exclusion and underrepresentation of women in medical research constitutes what the bioethical literature characterises as a form of scientific misconduct that produces harm through epistemological exclusion. Several decades ago, women of childbearing potential were systematically excluded from clinical trials, a practice justified by paternalistic beliefs about reproductive safety.[1] Although ad hoc policy bans on this exclusion began to be introduced in

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[1] Sumaiya Matin et al., *Gender Bias in Clinical Trial Enrollment: Female Authorship Matters*, 95 ANNALS OF VASCULAR SURGERY 233 (2023).

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the 1990s, structural misogyny persists. Women remain significantly underrepresented in trials of conditions that are disproportionately female: they constitute 42 percent of trial participants for psychiatric-disorder treatments although they are 60 percent of patients with such disorders, and 41 percent of cancer-trial participants although they are 51 percent of cancer patients.[2]

Such underrepresentation has damaging effects on several levels. In clinical terms, it produces a lack of knowledge about sex-specific and gender-specific pharmacokinetics, dose requirements, and adverse drug reactions related to women's physiology. At the institutional level, it mirrors and entrenches an epistemology that treats the male as the default research subject in biomedical science.[3] At the legal level, it demonstrates the inadequate implementation of existing regulatory requirements and the absence of effective accountability frameworks. These problems are made more acute in the Indian setting by social influences such as patriarchal social structures, gender-based constraints on women's autonomy, unequal access to healthcare facilities, and weak enforcement of established ethical principles.[4]

This paper undertakes a systematic analysis of research gaps, legal frameworks, and institutional failures, followed by the proposal of reform pathways. The discussion shows that gender bias in medical research is not merely an individual bias but a systemic one, embedded in the design of research, regulatory review, ethical gatekeeping, and incentive systems. Serious reform must therefore be addressed at several levels: legislative requirement, regulatory implementation, institutional transformation, and epistemological refocusing.

II. RESEARCH GAPS

A. Sex-disaggregated data deficiency

The most fundamental research gap involves the absence of systematic sex-disaggregated reporting and analysis in clinical trials and biomedical research more broadly. A 2022 analysis of 1,433 clinical trials encompassing over 300,000 participants found that women constituted only 41.2 percent of enrollees on average.[5] More critically, even where women are enrolled, sex-based analysis of efficacy and safety outcomes remains inconsistent. The guidance documents of the United States Food and Drug Administration (FDA), while recommending

[2] Labiotech.eu, *Women in Clinical Trials: Why Are They Still Underrepresented?* (Mar. 10, 2025), https://www.labiotech.eu/in-depth/women-clinical-trial/.

[3] See generally Cordelia Fine, *Testosterone Rex: Unmaking the Myths That Bind Us* (2017).

[4] Agrim Jain, *Gender Disparities in Clinical Trials: A Call for Equity*, LINKEDIN PULSE (Dec. 17, 2024), https://www.linkedin.com/pulse/gender-disparities-clinical-trials-call-equity-agrim-jain-edqzc.

[5] Medidata, *Women in Clinical Trials: History* (2025), https://www.medidata.com/en/life-science-resources/medidata-blog/women-in-clinical-trials-history/.

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analysis of pharmacokinetic differences between the sexes, do not mandate such analysis as a condition of trial approval.[6]

This gap produces what the literature terms systematic epistemic injustice, the structural exclusion of women's experiences and bodies from medical knowledge production.[7] Where sex-disaggregated analysis is absent, researchers cannot identify sex-specific adverse reactions, differential efficacy rates, or dosing requirements. Consequently, women receive medications developed and tested primarily on male subjects, often at dosages calibrated for male physiology.

B. Disease-specific underrepresentation

Certain disease categories demonstrate particularly acute underrepresentation. Cardiovascular research provides the paradigmatic case: for decades, women were excluded from cardiac research despite heart disease being the leading cause of death for women globally.[8] This exclusion was justified through outdated claims that women's hormonal fluctuations would compromise research validity. The consequence was a clinical blindness regarding how heart disease presents differently in women, its risk factors, and optimal treatment approaches.[9]

Mental-health research demonstrates a similar disparity. Women constitute 60 percent of patients with psychiatric disorders yet only 42 percent of psychiatric-trial participants.[10] Conditions such as endometriosis, which affects an estimated 10 percent of women of reproductive age, remained understudied for years partly because research prioritised male-centric disease categories.[11]

C. Intersectional erasure

A further research gap involves the failure to examine how gender bias intersects with other dimensions of systematic exclusion. Women participating in trials are typically younger, wealthier, more educated, and more frequently drawn from privileged communities than the general population.[12] This creates what intersectional feminist theory identifies as nested exclusions, in which women already marginalised through poverty, race, caste, disability, or

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[6] U.S. Food & Drug Admin., *Evaluation of Sex-Specific Data in Medical Device Clinical Studies: Guidance for Industry and FDA Staff* (2014) (non-binding recommendations).
[7] Shirin Heidari et al., *Sex and Gender Equity in Research: Rationale for the SAGER Guidelines and Recommended Use*, 1 RESEARCH INTEGRITY & PEER REVIEW 2 (2016).
[8] See Nieca Goldberg, *Women Are Not Small Men: Life-Saving Strategies for Preventing and Healing Heart Disease in Women* (2002).
[9] *Id.*.
[10] Labiotech.eu, *supra* note 2.
[11] *Id.* (noting an 8 to 9 year diagnostic delay for endometriosis).
[12] See Thomas Saphner et al., *Clinical Trial Participation Assessed by Age, Sex, Race, Ethnicity, and Socioeconomic Status*, 103 CONTEMPORARY CLINICAL TRIALS 106315 (2021).

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other dimensions face compounded exclusion from research participation. In the Indian context, rural women, Dalit women, women with disabilities, and women from religious minorities experience multiple barriers to research participation.

D. The sex and gender distinction gap

Biomedical research predominantly focuses on sex (biological categories) while largely neglecting gender (socially constructed categories of meaning and power). Yet gender significantly influences research outcomes: access to healthcare, the ability to consent autonomously, occupational exposures, social stress, and treatment-seeking behaviour all vary by gender. Research gaps exist regarding how gendered social conditions affect medication efficacy, side-effect tolerance, and health outcomes, and these gaps are particularly acute in the Indian context, where gender norms significantly restrict women's mobility, economic autonomy, and decision-making power.

III. Research questions

This paper is guided by the following questions. First, which laws and regulatory provisions have effectively been used to compel the inclusion of women in clinical trials, and why does enforcement remain lacking even where a mandatory provision exists? Second, what do Indian regulatory regimes, namely the Drugs Controller General of India regulations, ICMR guidelines, and ethics-committee frameworks, provide on gender equity in research, and where are the areas of enforcement deficiency? Third, what institutional, economic, social, and epistemological barriers perpetuate gender bias in biomedical research that are not directly addressed by legal prohibitions?

Fourth, how do the interactions between gender and sex differences produce differences in research outcomes, and why does the available biomedical research fail to interrogate that interaction? Fifth, what reform mechanisms would not only include women as formal research subjects but also fundamentally transform research questions, methodology, and analytical frameworks? Sixth, what role do intersectional dimensions (caste, class, disability, religion, sexuality) play in compounding gender-based exclusion in research in the Indian context?

IV. Research objectives

This study pursues six objectives: to document the extent and impact of gender bias in contemporary medical research using recent empirical evidence (2022 to 2025); to identify legal and regulatory tools for managing research inclusion in comparative perspective (international frameworks and India-specific tools); to examine the structural processes that sustain gender

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bias beyond formal policy, such as institutional culture, research incentives, and epistemological systems; to analyse the Indian context in particular, including its regulatory frameworks, sociocultural factors, and their intersection with caste, class, and religious dimensions; to develop broad reform proposals addressing legislative requirements, regulatory enforcement, institutional reform, and epistemological readjustment; and to engage with scholarship on health law, feminist jurisprudence, and their intersections with global-justice theory.

V. Central analysis and discussion

A. Legal architecture: global frameworks and implementation gaps

The inclusion of women in medical research became a legal requirement largely through the United States administrative system. The FDA guideline of 1977 effectively excluded women of childbearing potential from clinical trials, justified by reproductive paternalism.[13] This exclusion became institutionalised over roughly two decades, creating systematic epistemic gaps regarding women's health.

This approach was radically overturned by the NIH Revitalization Act of 1993, which requires that women and ethnic and racial groups be represented in NIH-supported research, and that minority women be examined for differences in their responses to interventions. This was a decisive legal shift from exclusion to inclusion. Crucially, however, the Act did not provide an enforcement mechanism, a penalty provision, or an accountability structure.[14]

This weakness led to further regulatory clarifications. The FDA issued guidance publications concerning pharmacokinetic studies, requiring investigation of menstrual-cycle effects, contraceptive interactions, and sex-specific dosing needs.[15] The European Medicines Agency also created standards on sex-disaggregated data analysis. These guidance documents were advisory rather than binding, however, generating the type of enforcement gap observed in contemporary trial data.

B. Ethical frameworks

Gender equity is increasingly an ethical requirement in international guidelines. The *Declaration of Helsinki*, as amended on several occasions, now provides that special attention should be given to vulnerable groups, such as women whose autonomy may be limited.[16]

[13] U.S. Food & Drug Admin., *General Considerations for the Clinical Evaluation of Drugs* (1977).
[14] NIH Revitalization Act of 1993, Pub. L. No. 103-43, § 131, 107 Stat. 122, 133-34 (1993).
[15] U.S. Food & Drug Admin., *Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs* (1993).
[16] World Med. Ass'n, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (rev. 2013).

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Inclusion grounded in gender builds on the principles of the *Belmont Report* (respect for persons, beneficence, justice) that lie at the foundation of bioethical commitments.[17]

Sex-disaggregated reporting, gender analysis, and examination of sex-specific outcomes are all required by the SAGER (Sex and Gender Equity in Research) guidelines, which have been increasingly adopted by major journals and funding agencies.[18] These guidelines exercise strong soft power, since they are adopted by journals such as *The Lancet*, *Nature*, and *JAMA*, but they carry no hard enforcement mechanisms.

C. Indian legal and regulatory frameworks

The constitutional promise of gender equality in India rests on several provisions: Article 14 (equality before the law), Article 15 (prohibition of discrimination), and Article 21 (right to life and health).[19] The constitutional jurisprudence confirms that legislative frameworks must be evaluated in relation to these equality protections.[20]

Clinical research is primarily governed by the ethical guidelines of the Indian Council of Medical Research (ICMR) on biomedical research involving human participants, operating alongside the New Drugs and Clinical Trials Rules, 2019, which now serve as the governing instrument on the subject. Although these instruments are more progressive than their predecessors, they contain few clear stipulations on gender equity. Schedule Y to the Drugs and Cosmetics Rules takes an oblique approach to gender representation, requiring ethics committees to be mixed-gender; but this is a requirement on the composition of the committee, not on who participates in the trial itself.[21]

Three principal regulatory authorities control clinical research in India. The Central Drugs Standard Control Organisation (CDSCO) is the central authority responsible for reviewing and granting clinical-trial applications under the supervision of the Drugs Controller General of India (DCGI).[22] Sex-disaggregated reporting is not yet a prerequisite for CDSCO approval, which presents an enforcement gap when compared with FDA standards.

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[17] Nat'l Comm'n for the Prot. of Human Subjects of Biomedical & Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979).
[18] Heidari et al., *supra* note 7.
[19] INDIA CONST. arts. 14-15, 21.
[20] *National Legal Services Authority v. Union of India*, (2014) 5 SCC 438 (India).
[21] The Drugs and Cosmetics Rules, 1945, Schedule Y (India).
[22] The New Drugs and Clinical Trials Rules, 2019, G.S.R. 227(E), Gazette of India, pt. II sec. 3(i) (Mar. 19, 2019) (India).

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The ICMR provides ethical guidance in its National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.[23] These principles emphasise the fair selection of participants and take gender into account, yet implementation mechanisms are weak, and the primary enforcement bodies, the ethics committees, have limited and fluctuating resources.

Ethics committees (institutional review boards) operate under a system based on the New Drugs and Clinical Trials Rules, 2019, and the ICMR guidelines. Schedule Y recommends that ethics committees include lay persons and members with varied expertise; it does not, however, require expertise in gender medicine or feminist bioethics specifically.[24]

The Indian regulatory environment contains a number of serious gaps. First, there is no direct requirement that clinical-trial protocols contain sex-disaggregated analysis of safety and efficacy data.[25] This contrasts with FDA guidance documents, which stipulate such analysis (albeit without enforcement mechanisms). Second, the guidelines recognise women as a potentially vulnerable group entitled to additional protection but stop short of mandating their inclusion in studies that would ultimately benefit them.[26] This perpetuates a protective rather than a participatory paradigm. Third, there is little explicit treatment of intersectional dimensions, that is, how gender connects with caste, class, disability, and religious identity to influence research participation and outcomes.[27]

D. Machinery that reinforces gender bias

Beyond legal requirements, several structural processes sustain gender bias. The culture of biomedical research has been deeply institutionalised, with the male body as the default research object and male scientists predominantly in leadership.[28] A 2023 meta-analysis showed that, in trials with female first and senior authors, the proportion of female participants was higher than in male-authored trials, implying that research leadership significantly affects study design.

This is what feminist epistemologists call epistemic injustice, a systematic exclusion located not only in the prejudices of individuals but in the organisation of knowledge production itself. Where male researchers frame research questions, they often apply male-centred paradigms to women's health rather than investigating women's distinct health needs.

[23] Indian Council of Med. Research, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017).
[24] The Drugs and Cosmetics Rules, *supra* note 21.
[25] See Jain, *supra* note 4.
[26] ICMR, *supra* note 23.
[27] *Id.*.
[28] See Matin et al., *supra* note 1.

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Reproductive paternalism remains a further mechanism. Even after it formally ceased to justify the exclusion of women of childbearing age, the practice persists. Many sponsors and ethics committees remain reluctant to enrol pregnant women and women of childbearing potential, although regulations permit their inclusion with proper informed consent. In the Indian context, such paternalism overlaps with patriarchal family structures. Women's reproductive capacity has often been treated as family property rather than a matter of individual decision-making, making independent consent difficult. Research protocols may demand spousal consent to include women in a study, which directly contradicts the concept of autonomous consent while purporting to safeguard reproduction.

Economic and logistical barriers are equally significant. Participation in research takes time, transportation, childcare, and literacy in research protocols. Each of these dimensions presents systematically higher obstacles for women in India. Rural women often lack access to transport, have limited autonomous mobility, and bear a disproportionate share of unpaid work. The time cost of trial participation is especially acute for women, who in most settings perform the majority of unpaid care labour. These obstacles are not resolved by legal orders; they require structural measures in research design, compensation, location, and timing.

Informed-consent deficits compound these barriers. The principle of informed consent assumes that participants understand research procedures, risks, and benefits in terms meaningful to them. Yet studies indicate that consent processes often fail to address sex-specific risks or gender-specific implications adequately. This is exacerbated in the Indian context, where consent forms are frequently provided only in English or Hindi rather than in languages participants read fluently, and where consent procedures fail to account for gendered decision-making patterns within families.

E. Consequences of gender bias: epistemic, clinical, and social

The clinical consequences are severe. Women are frequently prescribed drugs formulated and tested on men, with dosages calibrated to male physiology. The classic example is aspirin therapy: clinical studies demonstrated efficacy in preventing myocardial infarction but not stroke in men. Later studies using sex-disaggregated analysis showed that women receive stroke-prevention benefits from aspirin but not myocardial-infarction prevention, a sex-specific difference overlooked in male-centred studies. Cardiovascular drugs likewise tend to show

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varying efficacy in women and men, and these variations are not evident when studies omit sex-specific analysis.[29]

Adverse drug reactions occur in women at roughly 1.5 to 2 times the rate seen in men across most categories of medication.[30] Yet these sex-specific responses remain understudied. Pharmacokinetic differences (absorption, distribution, metabolism, excretion) vary substantially by sex owing to differences in body composition, gastric pH, hormonal effects on metabolism, and other factors. Where trials enrol insufficient proportions of women, or omit sex-specific analysis, such effects are discovered only through post-market surveillance, in some cases decades after a drug is approved.

Gender bias in research also perpetuates wider health disparities. Where research fails to address women-specific conditions or sex-specific disease manifestations, clinical knowledge remains inadequate. Women are then treated on the basis of incomplete evidence, leading to delayed diagnoses, inappropriate treatment, and poorer health outcomes. This overlaps with existing gender-based health inequities in the Indian context. One dimension of gender-based health disadvantage operates through India's maternal-mortality ratio, which remains among the highest in the world.[31] Such inequities are compounded by gender bias in non-reproductive health research.

Finally, there is epistemological harm. Feminist philosophers define epistemic harm as a category of injustice arising from exclusion in the production of knowledge.[32] The absence of women as research participants and subjects ensures that their experiences are absent from biomedical knowledge. This is what is termed testimonial injustice, the systematic devaluation of women's testimony about their own health experiences.[33] This epistemological violence reinforces wider social misogyny by institutionalising it, repeatedly signalling that women, their experiences, and their bodies are less deserving of scientific attention and rigour than men's. It amounts to institutional misogyny within medical institutions.

[29] See Jeffrey S. Berger et al., *Aspirin for the Primary Prevention of Cardiovascular Events in Women and Men: A Sex-Specific Meta-Analysis of Randomized Controlled Trials*, 295 JAMA 306 (2006).
[30] See Irving Zucker & Brian J. Prendergast, *Sex Differences in Pharmacokinetics Predict Adverse Drug Reactions in Women*, 11 BIOLOGY OF SEX DIFFERENCES 32 (2020).
[31] World Health Org. et al., *Trends in Maternal Mortality 2000 to 2020* (2023), https://www.who.int/publications/i/item/9789240068759.
[32] See Miranda Fricker, *Epistemic Injustice: Power and the Ethics of Knowing* (2007).
[33] *Id.*.

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VI. POLICY RECOMMENDATIONS

A. Legislative and regulatory reforms

As a prerequisite to CDSCO approval, India should implement a clear legislative directive mandating sex-disaggregated safety and efficacy data in every clinical trial. This requirement should mirror FDA guidance but carry the force of law, with defined consequences for non-compliance. Specifically, every clinical-trial protocol must define a sex-disaggregated analysis plan a priori;[34] all trial reports must contain sex-specific efficacy and adverse-event data; identified sex-based differences must be highlighted and incorporated into product labelling; and non-compliance should result in trial suspension and possible disciplinary penalties.[35]

CDSCO guidance should further establish that women constitute at least 40 to 50 percent of trial subjects in disease areas where women represent corresponding proportions of patients. This target should carry specific enforcement mechanisms: any deviation from inclusion targets must be justified to ethics committees; failure to meet targets without adequate justification should lead to rejection or modification of the protocol; regulatory approval should be conditioned on meeting inclusion targets, with documentation where they are not met; and drugs approved on the basis of insufficient female enrolment should be subject to heightened post-market surveillance.

Indian regulatory systems are weakly enforced, and reform should strengthen enforcement. This should include the creation of gender-equity units within CDSCO to review and implement gender-equity requirements; frequent audits of ethics committees examining adherence to gender-equity requirements; specific consequences for non-compliance, such as suspension of trials and disciplinary measures for researchers; transparency measures that publicise compliance and thereby enable accountability; and the power for ethics committees to require protocol changes to achieve gender equity.

B. Institutional and procedural reforms

India's ethics-committee system requires substantial capacity building. Recommendations include mandatory training on gender medicine and feminist bioethics for all ethics-committee members; the inclusion of gender-specific expertise on ethics committees; standardised assessment instruments enabling ethics committees to evaluate proposed trials for gender bias; a requirement that ethics committees document the sex-specific questions posed and the

[34] See FDA, *supra* note 6.
[35] Jain, *supra* note 4.

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adequacy of the protocol's responses; and regular monitoring and review of ethics committees through quality-improvement programmes.

Research institutions must also adopt inclusive design principles that address barriers to women's participation. Trial scheduling and location should accommodate women's time constraints and mobility difficulties; lost income and childcare costs should be reasonably compensated; informed-consent procedures should ensure genuine understanding in participants' preferred languages; childcare and transportation services should be offered where necessary; and reproductive autonomy should be recognised as including the right to participate in research, not merely the right to refuse.

Medical training and research should be reformed to incorporate compulsory education in gender medicine and sex-specific pharmacology in medical-school curricula; the integration of gender-equity considerations into research-training courses; funding incentives that favour trials addressing gender-specific health problems or demonstrating strong female representation; and recognition of contributions to gender equity in promotion-eligibility criteria.

C. Substantive and epistemological reforms

Reform must also address the content, priorities, and processes of research-agenda development. India must invest in agendas that specifically address gender-differentiated disease manifestation and treatment response; the aetiology and prevention of gender-specific diseases; intersectional dimensions affecting health (caste, class, disability, sexuality, religious identity); historically underfunded women's conditions (endometriosis, menopause, reproductive-autonomy issues); and gender-based violence and the health effects of social patriarchy.

Intersections of gender with other dimensions of identity and marginalisation must be studied systematically. Recommendations include a requirement that research proposals identify and examine intersectional dimensions; the disaggregation of results across more than one dimension at once (not only sex-disaggregated but also caste-disaggregated, religion-disaggregated, and so on); the involvement of marginalised communities in research design and interpretation; and the use of intersectional feminist theory to identify compounding exclusions.

VII. Conclusion

Gender bias in medical research remains one of biomedical science's most significant failures: the systematic exclusion of women from the production of knowledge about women's health.

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This exclusion offends scientific integrity (sex-specific data is necessary for valid science), medical ethics (justice requires equitable research participation), and human rights (women have rights to health and to participate in research that benefits them).

India presents both significant potential and significant challenges. Indian regulation has advanced considerably from earlier versions, but substantial gaps remain between international standards (such as FDA guidance) and Indian regulatory practice. The Indian situation has distinctive problems (patriarchal social structures, the intersectional complexities of caste and class, and resource constraints) and distinctive advantages (the engagement of feminist scholars and health advocates, and a constitutional commitment to gender equality).

Real reform requires interventions at multiple levels: a legislative mandate defining non-negotiable requirements, regulatory enforcement that provides accountability, institutional changes that facilitate participation, personnel training that embeds gender equity as ordinary scientific practice, and an epistemological shift that places women's health and experiences at the centre of biomedical research rather than at its margin.

The basic point is straightforward: women are half of humanity and the majority of healthcare users, and the diseases that affect them deserve thorough investigation. The participation of women in research that produces knowledge about women's health is not merely desirable; it is a necessity of scientific integrity, ethical research, and social justice. Legal frameworks must advance from suggestions to mandates, and from soft guidance to enforceable requirements.

By embedding gender equity as the foundation of its regulatory structures, ethics frameworks, and research institutions, India's medical-research sector can become a global leader in gender-equitable research. This is achievable only with sustained commitment, adequate resources, trained personnel, and a readiness to confront institutional inertia. The stakes are high: the question is whether India's medical research produces knowledge that genuinely benefits the health of all its citizens, or continues to exclude women structurally, harming them while claiming scientific objectivity.

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