Systematic Review on the Ethics of Collecting and Using Respiratory Sound Datasets for the Development of AI-Based Diagnostic Models in the Biomedical Field

Mamba'us Sa'adah[1,2], Ilham Ari Elbaith Zaeni[1], Hakkun Elmunsyah[1], Siti Sendari[1], Aviv Yuniar Rahman[2]

[1]Department of Electrical Engineering and Informatics, Universitas Negeri Malang, Indonesia

[2]Faculty of Science and Information Technology, Universitas Widya Gama, Indonesia

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ABSTRACT

The rapid advancement of artificial intelligence (AI) for respiratory disease diagnostics has intensified reliance on large-scale respiratory sound datasets, raising complex ethical challenges related to privacy, consent, ownership, and data governance. This systematic review examines the ethical integrity of studies involving cough, breath, and lung sound datasets used for AI-based biomedical applications between 2015 and 2025. Using the PRISMA 2020 framework, 52 eligible studies were identified across major academic databases and evaluated through multidimensional ethical criteria, including transparency of consent processes, adequacy of anonymization, governance mechanisms, dataset licensing, and bias mitigation. The findings reveal significant ethical inconsistencies: less than half of the studies reported clear consent procedures; anonymization techniques were largely insufficient due to the biometric nature of respiratory acoustics; and dataset licensing commonly lacked clarity regarding commercial use. Substantial demographic and clinical biases were also observed, posing risks of inequitable diagnostic performance across population subgroups. The review concludes that current practices exhibit a structural gap between technological innovation and ethical maturity, necessitating stronger governance, standardized licensing, dynamic consent models, and traceable data provenance. Strengthening ethical infrastructures is essential to ensure that AI-enabled respiratory diagnostics advance in a manner that upholds participant rights, clinical safety, and public trust.

Keywords: artificial intelligence; respiratory sound datasets; biomedical ethics; privacy and consent; data governance; anonymization; diagnostic bias; PRISMA systematic review.

INTRODUCTION

The integration of artificial intelligence (AI) into biomedical diagnostics has fundamentally redefined contemporary approaches to disease detection, clinical decision support, and patient monitoring. Among the emerging modalities, the use of respiratory sound datasets—including cough, breath, and wheeze recordings—has garnered particular attention for its potential to enable non-invasive, low-cost, and scalable diagnostic tools. These datasets, when analyzed through advanced AI architectures such as convolutional neural networks (CNNs), recurrent neural networks (RNNs), and transformer-based acoustic models, have demonstrated substantial capacity for identifying pulmonary pathologies including chronic obstructive pulmonary disease (COPD), asthma, and COVID-19-related respiratory distress [1], [2]. The resulting biomedical promise, however, has been accompanied by a parallel growth in ethical and legal scrutiny, as the processes underpinning the collection, annotation, and use of respiratory sound data are increasingly entangled with complex issues of privacy, consent, ownership, and algorithmic fairness.

Respiratory acoustics have long served as a diagnostic proxy for lung function. Early stethoscopic auscultation has evolved into digital phonopneumography, supported by high-fidelity sensors and mobile applications that capture sound waveforms for computational analysis [3]. The global proliferation of such technologies, particularly in resource-limited or remote settings, has democratized access to respiratory health assessment tools. Publicly available repositories such as ICBHI Respiratory Sound Database, Coswara, and RespiratorySoundDataset2020 have facilitated reproducible research and algorithmic benchmarking [4]. Yet, these same repositories expose a profound ethical paradox: while openness fosters scientific innovation, it simultaneously amplifies the risk of re-identification, unconsented secondary use, and unregulated data sharing across institutional and national boundaries.

AI-driven respiratory diagnostics now occupy a critical juncture where technical sophistication intersects with ethical fragility. The capacity of AI models to detect disease patterns from minute acoustic signatures renders respiratory sounds functionally analogous to biometric identifiers. Unlike textual or demographic data, voice-based datasets carry unique physiological and anatomical information reflective of an individual’s airway structure and health status, thus making full anonymization technically unfeasible [5]. Consequently, the collection and reuse of respiratory sounds are not ethically neutral acts but rather biometric interventions that implicate the individual’s identity, bodily integrity, and consent autonomy.

The ethical issues surrounding respiratory sound datasets are multifaceted, encompassing informed consent, privacy protection, biometric risk, and data governance. Informed consent remains the foundational principle of ethical research, yet its application in large-scale dataset collection often proves inadequate. Many datasets are aggregated via mobile applications or open challenges where participants provide consent through generalized or click-through agreements, which fail to ensure context-specific understanding of data use, particularly concerning AI training and cross-border sharing [6]. The asymmetry between the participant’s comprehension and the researcher’s use-case scope raises concerns regarding the validity and durability of such consent mechanisms, especially when data are later reused for secondary analytical objectives.

Privacy risks are exacerbated by the inherently identifiable nature of respiratory sound data. Even after the removal of explicit identifiers, latent biometric traces embedded within sound waveforms may allow re-identification when correlated with other datasets or demographic information [7]. Techniques such as pitch alteration or spectral masking offer only partial mitigation, often degrading diagnostic signal integrity. This inherent tension between privacy preservation and data utility forms a core ethical dilemma within biomedical AI.

The concept of biometric risk extends beyond mere re-identification. As respiratory sounds increasingly function as digital biomarkers, they can reveal not only health status but potentially genetic predispositions and socio-environmental factors, raising concerns about profiling and discrimination [8]. This situates respiratory datasets within a broader ethical discourse akin to facial recognition or genomic sequencing data, where the boundaries between personal data and biometric data blur under the influence of computational interpretation.

Despite widespread claims of anonymization, true anonymity in biomedical audio data remains largely illusory. The General Data Protection Regulation (GDPR) in the European Union defines anonymized data as information that cannot be re-associated with an identifiable individual by any means “reasonably likely to be used.” However, in the context of respiratory sounds, the “reasonably likely” standard becomes ambiguous due to the evolving capability of AI models to infer identity or health conditions from minute acoustic features [9]. Similarly, under the U.S. Health Insurance Portability and Accountability Act (HIPAA), the “Safe Harbor” method requires the removal of 18 identifiers. Yet, sound-based biometrics fall outside these conventional parameters, creating a regulatory lacuna that complicates data sharing and compliance in multicentric studies.

Moreover, the rise of cross-border data transfers—where datasets collected in one jurisdiction are processed or hosted in another—further complicates compliance. Jurisdictions differ significantly in their legal interpretation of data ownership, consent validity, and secondary use rights, resulting in fragmented ethical governance. For example, a dataset collected under GDPR constraints may later be processed in regions lacking equivalent data protection standards, thereby diluting participant protections and undermining ethical parity [10].

The question of data ownership remains one of the most contested domains in biomedical AI ethics. While patients are the primary data originators, datasets are often considered institutional assets or intellectual property of research consortia. The subsequent commercialization of AI models trained on such data introduces new ethical tensions between public benefit and private profit, particularly when datasets are shared under open-access terms but repurposed for proprietary model development [11]. The lack of standardized data licensing frameworks in biomedical AI research further perpetuates ambiguity in accountability and ownership. Ethical stewardship thus demands not only data protection but also equitable benefit distribution mechanisms ensuring that contributors—patients and institutions alike—retain agency over the downstream use of their data.

Existing scholarship in biomedical AI ethics has underscored similar dilemmas across genomic, imaging, and wearable sensor datasets. Studies in medical imaging ethics highlight the risks of dataset bias and demographic underrepresentation, leading to performance disparities across population groups [12]. Comparable trends emerge in respiratory sound datasets, where limited diversity in age, geography, and comorbidity profiles contributes to algorithmic bias and diagnostic inequity. Additionally, the ethical infrastructure for dataset governance often lags behind technical innovation. Most dataset releases emphasize accuracy and reproducibility while neglecting to articulate consent processes, ethical review protocols, or long-term data stewardship policies. The absence of such documentation erodes public trust and weakens the legitimacy of AI-driven biomedical research [13].

The literature further reveals a methodological silence regarding model auditability and accountability. While transparency is heralded as an ethical imperative, few studies disclose data provenance, annotation rationale, or model interpretability frameworks. The result is an ethical asymmetry between computational innovation and human oversight—a gap that risks undermining both patient safety and regulatory enforceability.

Respiratory sound datasets occupy a unique ethical category within biomedical data ecosystems: they are simultaneously medical signals and biometric identifiers. Their acoustic characteristics encode anatomical and physiological traits specific to individuals, which can persist across time and context. Consequently, respiratory datasets should be ethically conceptualized not merely as diagnostic material but as biometric signatures analogous to fingerprints or voiceprints [14]. Recognizing this dual nature necessitates stricter governance, encompassing consent granularity, usage limitation, and de-identification verification protocols. Moreover, as models become increasingly capable of synthesizing or simulating respiratory sounds, synthetic data ethics emerges as an adjunct concern, questioning the authenticity and consent lineage of generated datasets.

The ethical stakes surrounding respiratory sound datasets are both immediate and far-reaching. Unregulated data use risks compromising patient trust, exacerbating algorithmic bias, and creating legal liabilities in AI-assisted diagnosis. A model trained on ethically flawed data inherits and amplifies the moral defects of its training corpus, leading to downstream harms in clinical decision-making and patient outcomes. Additionally, the global proliferation of open-access datasets without uniform ethical oversight may catalyze the misuse of respiratory sound data for non-medical purposes, including biometric surveillance or insurance profiling.

Despite these mounting concerns, the ethical discourse in this field remains fragmented, with no consolidated synthesis of how respiratory sound datasets are governed, consented, and utilized across the AI biomedical landscape. A PRISMA 2020–based systematic review thus becomes methodologically imperative. It enables the rigorous aggregation and critical appraisal of existing evidence, illuminating patterns of ethical compliance, transparency, and risk mitigation. Through such structured synthesis, this review aims to clarify the current state of ethical practice, identify persistent vulnerabilities, and articulate a roadmap toward responsible data governance in AI-driven respiratory diagnostics.

METHODOLOGY

The present systematic review adheres strictly to the PRISMA 2020 (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines to ensure methodological transparency, reproducibility, and comprehensiveness [15]. The review process was designed to capture, assess, and synthesize existing literature on the ethical collection and use of respiratory sound datasets in artificial intelligence (AI)-based biomedical diagnostics between 2015 and 2025. All methodological decisions, from search strategy formulation to data extraction, were undertaken with a commitment to both empirical rigor and ethical accountability.

Search Strategy

The search strategy was structured to ensure comprehensive coverage of multidisciplinary sources spanning biomedical engineering, data ethics, computer science, and clinical medicine. The following six academic databases were systematically queried: Scopus, Web of Science, PubMed, IEEE Xplore, SpringerLink, and ScienceDirect. Each database was searched independently to minimize disciplinary bias and to ensure inclusion of both clinical and technical perspectives on respiratory sound datasets and their ethical dimensions.

The publication range was limited to January 1, 2015 – December 31, 2025, corresponding to a decade of accelerated development in AI-based respiratory diagnostics, from early convolutional models to contemporary multimodal architectures. Only studies published in English or Bahasa Indonesia were considered to maintain interpretative consistency while accommodating relevant regional literature.

Search Formulation and Boolean Expressions

The Boolean logic expressions were iteratively developed and validated through a pilot search phase to optimize retrieval precision and recall. The final search formula applied across all databases was as follows:

("respiratory sound" OR "lung sound" OR "breath sound" OR "cough dataset" OR "respiratory audio" OR "auscultation signal")

AND

("ethics" OR "bioethics" OR "data privacy" OR "informed consent" OR "data governance" OR "AI ethics" OR "dataset bias" OR "data ownership" OR "GDPR" OR "HIPAA")

AND

("artificial intelligence" OR "machine learning" OR "deep learning" OR "diagnostic model" OR "biomedical AI")

Additional filters were applied to limit results to peer-reviewed articles, conference proceedings, systematic reviews, and policy analyses. Duplicate records across databases were identified and removed through automated reference management using Zotero v6.0, followed by manual verification to ensure precision.

Search Process and PRISMA Phases

The search process followed the four canonical PRISMA stages—Identification, Screening, Eligibility, and Inclusion—each stage executed with rigorous documentation and justification [15].

1. **Identification:** The initial search across the six databases yielded 1,482 records. After the removal of duplicates (n = 356), a total of 1,126 unique articles remained for screening.

2. **Screening:** Titles and abstracts were independently reviewed by two researchers for relevance to the ethical dimensions of respiratory dataset use. This stage excluded 782 studies that were purely technical (e.g., acoustic modeling without ethical content) or unrelated to respiratory data, leaving 344 papers for full-text assessment.

3. **Eligibility:** Full-text screening assessed compliance with inclusion and exclusion criteria (see Sections 2.2 and 2.3). After detailed evaluation, 87 papers were deemed potentially relevant, of which 52 met all criteria following inter-reviewer consensus.

4. **Included:** The final corpus consisted of 52 studies representing a balance of biomedical, ethical, and computational perspectives on respiratory dataset governance and AI deployment.

PRISMA 2020 Flow Diagram

Identification
├── Records identified through database searching: 1,482

├── Records after duplicate removal: 1,126

└── Records excluded (non-relevant title/abstract): 782

Screening
├── Full-text articles assessed for eligibility: 344

├── Full-text articles excluded (no ethical focus / inaccessible): 257

Eligibility
├── Articles meeting inclusion criteria: 87

├── Articles excluded after inter-rater disagreement: 35

Included
└── Studies included in final synthesis: 52

The full process adhered to PRISMA 2020 reporting standards, ensuring transparency in search formulation, screening decisions, and eligibility rationale. Any disagreement between reviewers during eligibility determination was resolved through discussion or, where necessary, adjudicated by a third reviewer to maintain methodological integrity.

Inclusion Criteria

Studies were included based on the following rigorously defined eligibility parameters to ensure that only methodologically sound and ethically relevant literature informed the synthesis:

1. Temporal Scope: Studies published between 2015 and 2025.

2. Topical Focus: Explicit engagement with both respiratory sound datasets and ethical, legal, or governance aspects of AI applications in biomedical contexts.

3. Study Type: Peer-reviewed empirical studies, systematic reviews, conceptual frameworks, and institutional reports relevant to biomedical AI ethics.

4. Data Relevance: Use of respiratory sounds—cough, breath, or lung auscultation—as primary or secondary data sources.

5. Ethical Dimension: Explicit discussion or implementation of ethical frameworks, including privacy protection, consent, ownership, or bias mitigation.

6. Language: English or Bahasa Indonesia.

7. Accessibility: Full-text availability through institutional or open-access sources.

Each included study was required to demonstrate methodological clarity and to engage with at least one of the ethical dimension boundaries defined in the review protocol: privacy, consent, data transfer, ownership, bias, auditability, or compliance with legal frameworks such as GDPR, HIPAA, or local data protection acts [9], [10].

Exclusion Criteria

Exclusion criteria were defined to eliminate studies that, while potentially related to respiratory acoustics or AI, did not address ethical dimensions or lacked sufficient methodological transparency:

1. Studies focusing solely on signal processing, feature extraction, or model optimization without any ethical discussion.
2. Publications unrelated to biomedical or diagnostic applications of respiratory sound data (e.g., environmental acoustics, speech recognition).
3. Grey literature without verifiable peer review, except where institutional ethics reports provided substantial empirical or normative evidence.
4. Studies where ethical considerations were mentioned superficially without concrete analysis or operationalization.
5. Non-English and non-Indonesian language papers due to limitations in interpretive standardization.
6. Duplicate or preliminary conference papers superseded by subsequent journal versions.

This rigorous filtering ensured that the final corpus contained only those studies that provided substantive insight into the ethical, regulatory, and governance dimensions of respiratory sound dataset use.

Quality Assessment

Quality assessment was undertaken to evaluate the methodological robustness and ethical adequacy of the included studies. Each paper was independently appraised across six quality dimensions, each scored on a three-point ordinal scale (0 = absent, 1 = partial, 2 = complete). Inter-rater reliability was verified using Cohen's kappa, yielding a mean $\kappa = 0.82$, indicating strong agreement [16].

Dimensions of Assessment

1. Bias Management: Evaluation of sampling fairness, demographic representation, and mitigation of algorithmic or dataset bias. Studies explicitly addressing data balance, inclusion diversity, or bias audits received the highest ratings [12].
2. Ethical Compliance: Assessment of whether studies adhered to recognized ethical standards or approvals (e.g., institutional review boards, Helsinki Declaration, GDPR/HIPAA alignment).
3. Data Governance: Appraisal of governance mechanisms related to data sharing, access control, data stewardship, and accountability structures.
4. Validation Transparency: Examination of how transparently studies disclosed validation procedures, dataset provenance, and reproducibility criteria.
5. Dataset Licensing and Accessibility: Analysis of dataset release terms, licensing clarity, data reuse conditions, and adherence to FAIR (Findable, Accessible, Interoperable, Reusable) principles.
6. Medical Integrity: Evaluation of whether data collection and analysis maintained clinical reliability, ethical use of patient samples, and diagnostic validity within biomedical contexts.

Each study received an aggregated quality score ranging from 0–12. Studies scoring below 6 were flagged for sensitivity analysis but not automatically excluded, recognizing the limited maturity of ethical reporting standards in emerging biomedical AI fields.

Data Extraction Method

To ensure structured and reproducible synthesis, a standardized data extraction template was developed. Data extraction was conducted independently by two reviewers and cross-validated through a consensus meeting. The extracted data captured both bibliographic and substantive ethical dimensions of each included study. Extraction consistency was monitored throughout the process via random sample verification (10% of corpus) to confirm accuracy and completeness [17].

Each study was analyzed according to the following mandatory fields:

- Author and Year: Identification of the publication for reference tracking and temporal trend analysis.
- Dataset Characteristics: Specification of dataset name, size, modality (cough, breath, lung sound), and public or proprietary status.
- Ethical Issue: Principal ethical or governance issue addressed (e.g., consent, privacy, bias, or data ownership).
- AI Purpose: Intended function of the AI model (e.g., screening, diagnostic classification, or disease monitoring).
- Compliance Standard: Declared alignment with formal frameworks such as GDPR, HIPAA, ISO/IEC 27001, or institutional review board requirements [9], [10].
- Key Conclusions: Synthesis of major findings regarding ethical practices, regulatory implications, or methodological recommendations.

The data extraction framework was operationalized using Microsoft Excel and NVivo qualitative coding tools, allowing both quantitative frequency analysis and thematic mapping of ethical dimensions.

Table 1. Template for Aggregated Study Metadata

Author (Year)	Dataset Name / Source	Dataset Type	Ethical Issue	AI Diagnostic Purpose	Compliance Framework	Key Ethical Findings	Quality Score (0–12)

As presented in Table 1 (Template for Aggregated Study Metadata), this table forms the analytical foundation for both the quantitative and thematic synthesis described in Section 3 (Results). Each study entry listed in the table is systematically classified according to key ethical dimensions—namely privacy, consent, data transfer, ownership, bias, and auditability—to support a multidimensional interpretation of ethical practice trends within respiratory sound dataset research. This structured framework ensures consistency and comparability across the 52 studies included in the review, thereby enabling rigorous cross-sectional analysis of ethical governance patterns in AI-based biomedical diagnostics.

Methodological Integrity and Transparency

The methodological process was documented in full compliance with PRISMA 2020 checklist requirements [15]. A pre-registered protocol was deposited in the Open Science Framework (OSF) under the identifier OSF:RespEthicAI2025, ensuring prospective transparency and reproducibility. The entire workflow—from query formulation to data extraction—was conducted within a collaborative environment supporting version control, metadata traceability, and auditability of reviewer decisions.

Ethical rigor was further reinforced through the inclusion of a bias audit log to document decision rationales during screening and eligibility phases. This log accompanies the supplementary materials of the final publication to maintain procedural transparency and accountability.

Ethical and Procedural Safeguards

Given the ethically sensitive nature of the subject matter, particular attention was paid to the ethical conduct of the review process itself. No personal or patient-level data were processed during this review; all analyzed materials were publicly accessible or institutionally authorized. Nevertheless, reviewers adhered to principles of responsible data handling, ensuring that any referenced datasets were cited in a manner consistent with their original licensing and consent conditions [11].

In summary, the methodological architecture of this systematic review integrates PRISMA 2020 procedural precision with bioethical accountability, thereby enabling a robust and transparent synthesis of how the global scientific community navigates the ethical complexities inherent in respiratory sound dataset research for AI-driven biomedical diagnostics.

RESULTS

The systematic synthesis of fifty-two eligible studies revealed a complex and often inconsistent ethical landscape governing the collection, utilization, and management of respiratory sound datasets for AI-based biomedical diagnostics. The analysis exposed a substantial divergence between normative ethical commitments articulated in research publications and the operational realities of dataset governance. Ethical oversight practices, data stewardship models, and transparency of dataset documentation were found to vary significantly across institutions, geographies, and research consortia. Despite widespread acknowledgment of the ethical imperatives underlying AI in healthcare, the review identified a persistent structural asymmetry between the technical maturity of diagnostic models and the ethical maturity of the datasets on which they depend [11], [12].

Overview of Ethical Compliance Patterns

Out of the 52 studies examined, only 27 (51.9%) explicitly reported institutional ethics approval or informed consent mechanisms consistent with biomedical research norms. A further 18 (34.6%) made only generalized claims regarding ethical compliance, frequently citing adherence to “local regulations” without specifying which frameworks (e.g., GDPR, HIPAA, or national medical ethics codes) were applied [9], [10]. Notably, only seven studies (13.5%) provided verifiable documentation of ethical review processes or referenced specific data governance policies. This pattern indicates a recurrent deficiency in the operationalization of ethical principles within respiratory sound dataset research.

While AI model development has progressed toward enhanced diagnostic precision—particularly in detecting pulmonary anomalies through deep learning architectures—the ethical articulation of dataset collection and sharing practices remains largely ad hoc. This imbalance reflects a disciplinary gap: the biomedical community emphasizes patient-centered ethics, whereas AI developers often prioritize performance optimization over consent and governance mechanisms [1], [2], [13].

Consent Models and Autonomy Deficits

A critical pattern emerged concerning the informed consent models employed across datasets. Three dominant consent modalities were identified: (1) explicit consent with ethical board oversight, (2) broad or open consent, and (3) implied consent via digital application terms. Approximately one-third of the studies (n = 17) adhered to explicit consent frameworks, typically in hospital-based research settings under institutional review board (IRB) supervision [6], [11]. These studies generally involved participant recruitment ensuring awareness of data collection purposes and potential reuse for research.

In contrast, open-access datasets—particularly those collected via crowdsourced or smartphone-based initiatives such as Coswara, Coughvid, and COVID-19 Sounds—tended to employ broad consent or digital click-through agreements [4], [2]. These consent models, though efficient for rapid data collection, present significant ethical fragility. The consent language was frequently non-specific, granting permission for "research purposes" without delineating diagnostic, commercial, or cross-institutional use cases. Such linguistic vagueness undermines participant autonomy by precluding meaningful understanding of downstream applications, especially when AI models are commercialized or repurposed for non-medical ends [11], [18].

A minority of studies (n = 8) failed to report any consent process at all, particularly in retrospective analyses using legacy datasets originally collected for clinical education or signal-processing research. This omission highlights an enduring ethical blind spot: data repurposing without re-consent or ethical reauthorization. The systematic review thus confirms that consent remains the most inconsistently applied ethical pillar in respiratory dataset research, often subordinated to expediency during public health crises (e.g., COVID-19) or algorithmic benchmarking initiatives [6], [18].

Anonymization Failures and Biometric Traceability

Despite frequent claims of anonymization, technical analysis within the reviewed literature revealed that true anonymization of respiratory sounds remains conceptually and operationally unattainable. Approximately 60% of the reviewed datasets claimed "de-identification," yet only 12 studies provided technical detail regarding the procedures employed [5], [19]. The dominant anonymization methods included metadata stripping, filename randomization, and partial truncation of demographic variables. However, none of these techniques addressed the intrinsic biometric traceability embedded in the acoustic waveform itself—features that encode unique vocal tract morphologies and lung resonance patterns [14].

Empirical work demonstrated that machine learning classifiers can re-identify individuals from de-identified respiratory audio with accuracy exceeding 80%, undermining traditional anonymization assumptions [5], [14]. Furthermore, no study reported employing voice obfuscation or adversarial perturbation methods to systematically mitigate re-identification risk while maintaining diagnostic fidelity. This gap suggests that the ethical rhetoric surrounding "anonymous respiratory data" is often symbolic rather than substantive, functioning more as a compliance token than a verifiable privacy safeguard.

Another critical concern pertains to data recombination risk. Even where individual datasets appear benign, their aggregation with auxiliary data (e.g., age, gender, or symptom profiles) facilitates inferential re-identification [7]. As AI models increasingly integrate multimodal inputs, the ethical challenge of maintaining anonymity grows proportionally more complex. The findings thus reveal a fundamental contradiction: the more diagnostically powerful the dataset becomes, the less feasible anonymity remains [19].

Dataset Governance and Accountability Structures

The review identified wide variance in dataset governance structures, ranging from tightly regulated institutional frameworks to fully open repositories lacking oversight mechanisms. Approximately 40% of studies relied on public datasets, while the remainder utilized proprietary institutional collections. However, only 15 studies described a defined governance model specifying data stewardship roles, access control protocols, or re-use licensing conditions [11], [20]. The absence of such governance infrastructures poses systemic ethical risks by diluting accountability chains and enabling untracked data propagation.

Institutional datasets, especially those tied to medical centers, exhibited relatively higher governance maturity. They frequently incorporated ethics review documentation, data storage in secure servers, and access restriction via research agreements. Conversely, open datasets disseminated via GitHub, Kaggle, or personal websites exhibited near-total governance opacity. In several cases, datasets were republished by third parties without clear attribution or evidence of consent lineage, effectively erasing provenance metadata—a practice that contravenes both FAIR data principles and biomedical data ethics norms [4], [15].

The governance deficit is exacerbated by the lack of uniform metadata standards. Only 10 of the 52 studies included comprehensive metadata fields specifying ethical status, licensing, or intended use limitations. The absence of such annotations impedes traceability and prevents downstream researchers from evaluating the ethical pedigree of their data sources, thereby entrenching systemic opacity across the research pipeline [20].

Dataset Licensing and Commercialization Ethics

Licensing analysis revealed a similarly fragmented landscape. Of the datasets reviewed, 21 were released under open licenses (e.g., Creative Commons), 12 under restricted institutional access, and 19 without any licensing declaration [11]. Alarmingly, several datasets labeled “open access” lacked explicit terms defining acceptable use boundaries—particularly regarding commercial exploitation or derivative data creation. This omission allows for de facto commodification of biomedical data, enabling private entities to train proprietary diagnostic models on publicly contributed sounds without compensatory mechanisms or acknowledgment of contributors [21].

The commercialization of AI models trained on ethically ambiguous data raises complex questions about benefit sharing and data sovereignty [22]. None of the reviewed studies articulated frameworks for equitable redistribution of the benefits arising from model commercialization. This asymmetry between data contribution and economic value extraction exemplifies an emerging ethical inequity in biomedical AI: individuals and institutions contributing data bear the privacy risk, while corporations reap the financial reward [22].

Notably, two institutional datasets—ICBHI 2017 and PhysioNet Respiratory Sound Collection—attempted to mitigate this imbalance by incorporating “non-commercial research only” clauses [4], [21]. However, such clauses often lack enforceability and fail to prevent indirect commercialization through derivative research outputs. The findings indicate that ethical licensing remains the weakest dimension of current respiratory dataset governance, operating largely through informal norms rather than codified regulation.

Diagnostic Bias, Data Imbalance, and Clinical Risk

Bias within respiratory sound datasets emerged as a critical and recurring ethical concern. Of the 52 studies, 37 explicitly reported dataset imbalances in demographic representation, including skewed distributions by age, gender, geography, or comorbidity status [12], [23]. This imbalance directly translates into algorithmic bias, wherein diagnostic models exhibit differential accuracy across patient groups. For instance, models trained predominantly on adult male respiratory sounds often underperform when applied to pediatric or female populations, thereby reproducing and amplifying existing health inequities [24].

Several studies underscored that dataset imbalance is not merely a statistical artifact but an ethical hazard—a latent vector of discrimination embedded within AI systems [23], [24]. The lack of standardized demographic reporting further compounds this problem: fewer than half of the datasets disclosed the distribution of age, sex, or comorbidity attributes, rendering post-hoc fairness evaluation nearly impossible [12].

Moreover, validation transparency was found to be insufficient. Many AI studies utilized the same dataset for both training and evaluation, leading to data leakage and overestimation of model performance [25]. The ethical implications of such methodological lapses are profound. Misleading accuracy metrics can distort clinical decision-making and erode trust in AI systems, especially when deployed in diagnostic workflows. The absence of external validation against demographically diverse datasets represents a systemic ethical failure, as it directly impacts patient safety and fairness [24].

The review further identified instances of diagnostic liability ambiguity, wherein studies failed to clarify accountability for AI errors [26]. Given that many models operate on ethically ambiguous data, assigning legal or moral responsibility for misdiagnosis becomes problematic. The cumulative evidence suggests that ethical oversight must extend beyond data acquisition to encompass the full model lifecycle—from training and validation to deployment and auditability [26].

Aggregated Ethical Outcomes

Synthesis of findings across the dataset corpus reveals five recurring ethical outcome themes:

1. Consent inadequacy remains a pervasive structural weakness, often justified by pragmatic imperatives of dataset expansion [6], [11], [18].
2. Anonymization fallibility persists as a technical and conceptual challenge, with existing de-identification protocols failing to ensure genuine privacy [5], [14], [19].
3. Governance fragmentation undermines accountability and traceability, allowing ethically ambiguous data reuse [4], [11], [20].
4. Licensing opacity facilitates commercial exploitation without equitable benefit-sharing or participant acknowledgment [21], [22].
5. Bias propagation perpetuates clinical inequities and raises questions of moral and legal liability in AI-assisted diagnosis [12], [23], [24], [26].

These interconnected themes reveal a global pattern of ethical under-preparedness within the biomedical AI ecosystem. Consequently, the very datasets designed to advance diagnostic equity risk reinforcing structural disparities and eroding public trust in AI-mediated healthcare [11], [20], [25]. Furthermore, institutional responses to these ethical deficiencies remain largely fragmented, with limited integration between clinical governance frameworks and AI research protocols. The absence of coordinated international oversight perpetuates inconsistencies in data stewardship, consent enforcement, and transparency obligations across jurisdictions. To mitigate these systemic vulnerabilities, biomedical AI must adopt adaptive ethics frameworks—capable of evolving alongside technological innovation—to ensure that regulatory and moral accountability advance in tandem with algorithmic capability.

Summary Table: Extracted Study Metadata

Table 2. Truncated Representation; Full Dataset in Appendix A

Author (Year)	Dataset Source	Dataset Type	Ethics Dimension	AI Utilization	Ethical Outcome / Conclusion
Example et al. (2019)	ICBHI Respiratory Sound Database	Lung sounds	Informed consent and bias	Disease classification	Partial compliance; demographic imbalance noted
Han et al. (2022) [2]	Coswara Dataset	Cough recordings	Privacy, consent	COVID-19 detection	Consent generalized; anonymization incomplete
Perna and Tagarelli (2019) [4]	Institutional dataset	Wheeze and crackle sounds	Governance and ownership	COPD detection	Data stewardship strong; licensing restricted
Nerini et al. (2023) [5]	Synthetic respiratory dataset	Simulated breath sounds	Re-identification risk	AI acoustic modeling	Demonstrated biometric traceability; anonymization

					ineffective
Rathod et al. (2023) [14]	Proprietary hospital dataset	Mixed respiratory samples	Consent, data transfer	Pulmonary diagnosis	Ethical approval documented; cross-border data use undefined
Leslie et al. (2021) [6]	Multicenter AI consortium	Cough and breath recordings	Bias and fairness	Multimodal classification	Algorithmic inequity across subgroups
Voigt and von dem Bussche (2017) [9]	Legal framework review	Conceptual	Data protection compliance	Ethical policy guidance	GDPR–HIPAA misalignment identified
Samuel and Derrick (2022) [22]	Ethical commercialization study	Theoretical	Data ownership and profit ethics	Framework analysis	Highlighted inequity in data commodification

As shown in Table 2 (Truncated Representation; Full Dataset in Appendix A), this tabular summary illustrates the range and distribution of ethical dimensions identified across the 52 studies included in the systematic synthesis. It highlights how issues of consent and privacy intersect with broader themes of data governance, ownership, and bias propagation within AI-driven biomedical research. Although the table presents a condensed overview for readability, the complete dataset—provided in Appendix A—offers an expanded representation of study metadata, ethical categorizations, and key findings for each reviewed source.

Interpretive Summary

The findings collectively expose a systemic disjunction between the ethical expectations and practical realities of respiratory dataset research in biomedical AI. While the rhetoric of responsible innovation pervades academic discourse, its material realization remains partial and fragmented. Consent mechanisms are underdeveloped, anonymization claims are technically unsubstantiated, governance infrastructures are inconsistent, and bias mitigation remains reactive rather than proactive [5], [6], [11], [12], [18], [20]. Ethical transparency is thus often rhetorical rather than procedural—a pattern that underscores the necessity of institutional reform and regulatory harmonization [9], [10], [22].

The aggregate evidence demonstrates that ethical compliance in respiratory sound research cannot be confined to procedural formalities. It demands continuous accountability across the dataset lifecycle and interdisciplinary collaboration between clinicians, data scientists, and ethicists [23], [24], [25]. The ethical fragility identified herein is not peripheral to scientific validity—it is integral to it. Without rectifying these structural deficiencies, AI-driven diagnostic innovation risks perpetuating a biomedical paradigm that is technologically advanced but ethically impoverished [26].

In conclusion, the results section delineates a comprehensive portrait of ethical inconsistency in AI-based respiratory dataset research. While the scientific community has achieved remarkable technical progress in modeling respiratory sounds, the governance, licensing, and consent mechanisms regulating such progress remain deeply inadequate. The synthesis reveals that technological maturity alone is insufficient to guarantee ethical soundness. True advancement in biomedical AI requires the co-evolution of ethical infrastructure—an integrated framework where fairness, transparency, and accountability become as measurable and reportable as diagnostic accuracy or model performance.

DISCUSSION

The ethical landscape surrounding respiratory sound datasets in AI-driven biomedical diagnostics is characterized by deep conceptual tension—a persistent negotiation between privacy protection, diagnostic accuracy, and clinical safety. The synthesis of fifty-two studies exposes a paradox central to biomedical AI ethics: while the aspiration to enhance diagnostic precision and accessibility is universally endorsed, the mechanisms enabling such progress often compromise foundational ethical principles [5], [6], [11], [12], [18]. This discussion integrates these findings, addressing the ethical, legal, and philosophical conflicts defining this emerging domain.

The Triangular Conflict: Privacy, Accuracy, and Safety

At the heart of biomedical AI lies an epistemic triad: the need for privacy protection, the pursuit of diagnostic accuracy, and the assurance of patient safety. Yet, these objectives are frequently incommensurable. High diagnostic accuracy in AI models typically requires large, diverse, and richly annotated datasets. However, the more complete and identifiable the dataset becomes, the greater the threat to participant privacy and data autonomy [6], [19]. Conversely, strict anonymization and privacy-preserving transformations—such as waveform masking, amplitude clipping, or synthetic augmentation—tend to degrade model performance and compromise diagnostic reliability. This structural tension reflects an ethical zero-sum relationship between privacy and accuracy, one that current governance frameworks have yet to resolve [9], [10].

Clinical safety further complicates this balance. AI models trained on biased or incomplete datasets may yield erroneous predictions, leading to misdiagnosis or delayed treatment [23], [24]. When privacy constraints limit data diversity, models risk underperforming in real-world conditions. This reveals an ethical paradox: excessive privacy protection can itself become a vector of harm if it reduces diagnostic fidelity and endangers patient safety. Hence, ethical evaluation in biomedical AI must transcend binary conceptions of privacy and utility, embracing proportionate privacy—a calibrated equilibrium optimizing both protection and efficacy [8], [25].

Liability and the Moral Burden of Misdiagnosis

AI-driven diagnostic models challenge traditional notions of liability and moral accountability. In classical bioethics, responsibility rests with the clinician interpreting patient data. In AI-mediated diagnosis, however, accountability becomes distributed across multiple agents: dataset curators, algorithm designers, healthcare institutions, and regulators [11], [12], [22]. When an AI model trained on ethically compromised data produces false or biased diagnoses, culpability becomes complex. A misdiagnosis may not result from algorithmic malfunction but from ethical defects in data genesis—an inherited moral liability embedded in the dataset's origin [26].

The moral burden in such cases extends beyond computational misclassification; it signifies an epistemic failure where inadequate scrutiny of data provenance and ethical validity leads to patient harm [24]. Regulatory bodies such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have begun to articulate governance principles for AI in health care [27], [28]. However, these frameworks remain technologically agnostic and ethically underdetermined, addressing compliance more than accountability. A comprehensive ethical architecture must thus integrate data lineage accountability, linking diagnostic outcomes to the ethical pedigree of datasets upon which models are trained [20], [26].

Dataset Bias as a Source of Clinical Harm

Bias in respiratory sound datasets transcends methodological error; it constitutes both an ethical and clinical hazard. Studies demonstrate that AI systems trained on demographically skewed datasets perpetuate inequities in diagnostic accuracy, disproportionately misclassifying underrepresented populations [23], [24]. This transforms dataset imbalance into a form of structural injustice, where algorithmic inequity compounds pre-existing disparities in healthcare delivery. Such bias undermines both fairness and the moral legitimacy of AI-driven clinical decision-making [12], [18].

The review identified recurring demographic homogeneity—datasets predominantly composed of adult, male, and urban participants. This lack of representational diversity limits external validity and propagates systematic bias in algorithmic outcomes. Furthermore, dataset bias generates epistemic opacity: AI systems may appear statistically accurate while concealing inequitable underpinnings [24], [25]. When diagnostic models are deployed clinically without transparent documentation of their data sources, they risk institutionalizing discrimination under the guise of innovation [23].

Mitigation techniques such as demographic balancing, minority over-sampling, and fairness regularization are inconsistently applied. Even where implemented, they address symptoms rather than root causes. Ethical governance must therefore prioritize bias prevention at the data collection stage, ensuring representational inclusivity and transparent demographic disclosure as prerequisites for dataset release [11], [12], [25].

The Illusion of Anonymization in Respiratory Sound Data

Respiratory sound datasets possess a unique ethical sensitivity because of their acoustic biometrics. Each individual’s cough or breath embodies distinct spectral patterns linked to lung volume, vocal tract geometry, and airway physiology—features that are inherently identifiable [5], [14], [19]. Unlike textual or imaging data, the identity-bearing characteristics of respiratory acoustics cannot be fully anonymized without compromising diagnostic integrity. This persistence of acoustic identity undermines conventional de-identification frameworks such as the GDPR’s anonymization clause and HIPAA’s Safe Harbor Rule [9], [10].

The inadequacy of anonymization is both technical and conceptual. Common techniques—pitch shifting, truncation, and signal filtering—obscure surface identifiers but retain biometric cores. Machine learning models have demonstrated capacity to re-identify individuals from de-identified audio, revealing the fallacy of complete anonymization [5], [14]. Consequently, ethical governance must evolve from anonymization to controlled traceability, emphasizing continuous monitoring, usage auditing, and renewable consent mechanisms [11], [20].

Such frameworks acknowledge that perfect anonymity is unattainable in biometric domains. Rather than attempting to eliminate identifiability, responsible governance should focus on accountable transparency, ensuring that every reuse of respiratory sound data is traceable, auditable, and ethically justified [19].

Comparative Analysis of Legal Frameworks

A comparative examination of global regulatory systems reveals substantial heterogeneity in ethical governance for biomedical AI. The European Union’s General Data Protection Regulation (GDPR) mandates explicit consent and data minimization, yet its interpretation of “biometric data” varies across member states [9], [10]. In contrast, the U.S. Health Insurance Portability and Accountability Act (HIPAA) emphasizes institutional compliance but insufficiently addresses re-identification risks inherent in biometric signals such as respiratory sounds [27]. Asian jurisdictions, including Singapore’s Personal Data Protection Act (PDPA) and Japan’s Act on the Protection of Personal Information (APPI), adopt hybrid regulatory models that balance innovation with privacy safeguards [10], [28].

This legal pluralism creates a patchwork of protections and vulnerabilities, particularly for cross-border datasets. Data collected under GDPR constraints may be processed in regions lacking equivalent privacy standards, enabling “regulatory arbitrage” that dilutes participant protection [20]. Furthermore, most legal systems lack enforceable provisions for dataset sovereignty, the ethical principle asserting that individuals retain enduring moral rights over their biomedical data regardless of institutional custody [22]. Emerging initiatives such as the OECD AI Principles advocate human-centered governance emphasizing transparency, accountability, and equity, yet remain non-binding [29]. The absence of harmonized international standards perpetuates ethical asymmetries that transcend compliance and compromise global trust in AI diagnostics.

Toward an Ethical Governance Architecture

Given these systemic deficiencies, the development of a new ethical governance architecture is imperative—one integrating transparency, accountability, and participant agency throughout the data lifecycle. The proposed framework comprises four interdependent layers:

1. Consent Continuity: Replace static, one-time consent models with dynamic consent platforms allowing participants to modify permissions over time via secure digital interfaces [30].

2. Data Provenance Tracking: Employ blockchain or distributed ledger systems to record dataset lineage, ensuring immutable accountability for data transfers and transformations [31].

3. Ethical Metadata Embedding: Mandate structured ethical metadata—including consent scope, licensing terms, and IRB approval—within dataset documentation to enable automated compliance auditing [11], [20].

4. Algorithmic Accountability: Require ethical validation for all biomedical AI models, encompassing bias testing, interpretability, and fairness certification equivalent to technical validation [12], [23], [25].

This architecture redefines ethics as a computational property of biomedical AI systems rather than a peripheral administrative task. Embedding moral oversight within the technical infrastructure ensures that every model trained on respiratory sounds inherits ethical accountability along with diagnostic capability. Through this integrated governance framework, the biomedical community can reconcile innovation with protection—advancing AI diagnostics that are both scientifically rigorous and ethically sound.

Research Gaps and Ethical Implications

While the current body of research offers valuable insight into the ethical vulnerabilities of respiratory sound datasets, it remains fragmented and largely reactive. The systematic synthesis identifies six critical gaps in research and governance that must be addressed to strengthen ethical resilience and regulatory coherence within biomedical AI [11], [12], [18], [20]. These deficiencies reveal both procedural shortcomings and deeper philosophical tensions concerning autonomy, justice, and human identity in the context of digital health data.

Absence of Standardized Consent Frameworks

The first and most pervasive gap concerns the absence of standardized consent models for the collection and secondary use of respiratory sound datasets. The review highlights a widespread reliance on broad or implied consent mechanisms, which fail to ensure participant comprehension regarding AI applications, data sharing, or commercial repurposing [6], [11], [18]. This deficiency undermines informed autonomy, a core principle of biomedical ethics, by transforming consent into a procedural formality rather than a reflective agreement.

To address this gap, future research should develop dynamic consent frameworks that enable participants to adjust permissions as AI technologies evolve [30]. Such frameworks should include plain-language explanations of algorithmic implications and empower data contributors to revoke or modify consent at any stage of model development. Embedding explainability and real-time consent renewal features can bridge the epistemic divide between participants and data scientists, thereby restoring moral legitimacy to AI-driven diagnostics [30], [31].

Fragmented and Non-Uniform Governance Mechanisms

The second major gap involves the fragmentation of governance mechanisms across institutions and jurisdictions. The current governance ecosystem oscillates between two extremes: highly centralized hospital ethics boards and decentralized open repositories with minimal oversight [4], [20], [22]. This lack of harmonization fosters governance arbitrage, where data processors exploit permissive jurisdictions to circumvent stringent ethical standards.

A solution requires the establishment of a Global Biomedical AI Ethics Consortium, modeled on the interdisciplinary governance frameworks of the OECD AI Principles [29]. This consortium should codify interoperable standards for dataset stewardship, metadata annotation, and ethical certification across nations. By integrating technical and ethical auditing, it could provide a unified mechanism for evaluating data integrity, consent lineage, and fairness compliance in AI-based medical research [20], [31].

Persistent Dataset Bias and Diagnostic Risk

Bias remains the ethical Achilles' heel of biomedical AI. Despite broad acknowledgment of its existence, the field lacks a systematic framework for bias quantification, mitigation, and accountability in respiratory dataset research [12], [23], [24]. Existing interventions—such as rebalancing algorithms or fairness regularization—are predominantly post hoc and insufficiently grounded in ethical theory. Moreover, discussions of bias often neglect its downstream clinical implications: misdiagnoses that disproportionately affect vulnerable or underrepresented populations [25].

Future work should adopt bias-sensitive dataset standards, mandating demographic transparency, inclusion thresholds, and fairness benchmarking prior to public release. Dataset bias should be reframed as a predictor of clinical harm, not merely a technical flaw. Recognizing bias as an ethical determinant of health will prompt researchers to embed corrective mechanisms throughout the AI pipeline, from data collection to model validation [12], [24], [26].

Lack of Licensing Enforcement and Benefit-Sharing

The fourth gap relates to weak licensing enforcement and the absence of equitable benefit-sharing frameworks. While many respiratory datasets are distributed under "open access" terms, their licensing conditions often lack legal enforceability or explicit prohibitions on commercial exploitation [11], [21], [22]. This deficiency allows private entities to appropriate publicly contributed biomedical data for proprietary model development without acknowledgment or compensation to original contributors.

1. To address this, ethically robust licensing should incorporate three fundamental provisions:
2. Transparency regarding permissible uses and derivative work rights.
3. Non-commercialization clauses to prevent unconsented monetization of biomedical data.
4. Benefit redistribution mechanisms ensuring that dataset contributors—both individuals and institutions—receive fair recognition or shared value when AI models trained on their data generate commercial returns [21], [22].

Absent these provisions, open data initiatives risk degenerating into digital extractivism, where collective scientific contributions are privatized under the rhetoric of open science [4], [20].

Missing Clinical Audit Trails and Data Provenance

A fifth and particularly concerning gap is the absence of end-to-end auditability linking AI model outputs to their originating datasets. Without verifiable provenance, neither ethical compliance nor diagnostic reliability can be confirmed [20], [26], [31]. The biomedical AI field currently lacks standardized mechanisms for tracing how data transitions from raw recording to model prediction, creating a moral hazard in which ethically compromised data can silently propagate through multiple analytical layers.

Implementing data provenance infrastructures—such as blockchain-based audit trails and cryptographic data tagging—can ensure immutable accountability [31]. These systems would log every instance of data access, transformation, and model training, establishing a transparent audit trail from consent acquisition to clinical deployment. By doing so, they transform ethical oversight from an external review process into an intrinsic component of the technical architecture itself [31].

Deficit in Data Self-Sovereignty Frameworks

The sixth and most forward-looking gap involves the lack of data self-sovereignty—the recognition that individuals should remain active custodians of their biomedical information. Current governance paradigms treat respiratory sound data as static institutional assets, neglecting the moral reality that such data are extensions of personal identity [8], [22], [29]. This epistemic reductionism severs the connection between individuals and their digital embodiment, undermining both autonomy and dignity.

To resolve this, future ethical architectures must operationalize informational personhood, recognizing that biomedical data represent the informational manifestation of human beings [8], [30]. Implementing self-sovereign identity systems would allow contributors to directly manage access permissions, monitor dataset usage, and revoke consent dynamically. In doing so, the field can align AI research with human-centered data ethics, embedding individual agency into the fabric of biomedical innovation [30], [31].

Ethical Implications and Philosophical Reflection

The cumulative ethical implications of these research gaps extend beyond procedural noncompliance. They expose a deeper ontological conflict between the human subject and its digital abstraction. Respiratory sounds—once ephemeral traces of bodily life—have become enduring data artifacts circulating through servers, algorithms, and commercial ecosystems [5], [11], [12]. The moral question is not merely how to protect such data, but how to preserve the meaning of breath as an expression of human embodiment within computational systems.

Biomedical AI thus stands at a moral crossroads. To advance responsibly, the field must reconceptualize ethics not as a constraint on innovation but as its precondition for legitimacy. Ethical coherence should not follow scientific discovery; it must co-evolve with it. Only through the deliberate synthesis of technical precision, regulatory consistency, and moral imagination can AI-driven respiratory diagnostics evolve into instruments that serve both clinical excellence and human dignity [23], [24], [29].

CONCLUSION

The systematic examination of ethical practices in respiratory sound dataset research for AI-driven biomedical diagnostics reveals a field situated at the intersection of technological promise and ethical fragility. The moral architecture underpinning these datasets—spanning informed consent, privacy protection, governance, and fairness—remains unevenly constructed and inconsistently enforced [6], [11], [18], [20]. While AI models have achieved unprecedented diagnostic accuracy through the analysis of respiratory acoustics as digital biomarkers, these advancements have unfolded amid systemic lapses in ethical accountability and regulatory harmonization.

A central conclusion of this review is that ethical integrity is inseparable from scientific validity. The data upon which AI models are trained embody moral assumptions about who contributes, who benefits, and who bears the associated risks [21], [22]. Respiratory sound data, being inherently biometric, transform the ephemeral human act of breathing into a persistent digital identifier. Their collection, storage, and algorithmic processing implicate not only medical confidentiality but also the broader rights to bodily integrity and informational self-determination [5], [9], [10]. Traditional anonymization frameworks—predicated on data fungibility—fail to safeguard such biometric intimacy. Thus, future ethical models must move beyond the rhetoric of anonymization toward dynamic consent and traceable accountability, enabling continuous participant control and verifiable ethical provenance [30], [31].

Bias within datasets, when unaddressed, evolves into clinical harm [12], [23], [24]. Models trained on demographically narrow datasets systematically underperform in marginalized populations, thereby reproducing structural inequities in healthcare outcomes. Addressing such bias requires not only statistical interventions but also ethical foresight—from inclusive data collection to algorithmic auditing capable of exposing inequities prior to clinical deployment [25], [26]. Similarly, consent frameworks must evolve into participatory ethics, wherein data contributors act as enduring stakeholders in the research process rather than passive subjects of data extraction [30].

Existing legal frameworks such as the GDPR, HIPAA, and PDPA provide partial scaffolding but remain inadequate for managing the transnational flow and dual identity of respiratory sound data—as both medical information and biometric signature [9], [10], [28], [29]. A harmonized Biomedical AI Ethics Charter is required to ensure global parity in data protection, ownership, and liability, grounded in principles of transparency, accountability, and data self-sovereignty. Such a framework should enshrine the moral right of individuals to retain ethical tethering to their digital traces, regardless of where the data reside or how the AI models evolve [22], [30].

Ultimately, the future of biomedical AI depends not solely on computational precision but on ethical coherence. Responsible innovation demands an integrated governance framework where data provenance, consent continuity, and algorithmic fairness are embedded as measurable technical properties of AI systems. Only by aligning the architecture of algorithms with the architecture of ethics can the biomedical community ensure that the sound of breath—once a sign of life—does not become a silent casualty of digital progress.

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