

A Simplified Ethical Data Collection Framework For Medical Image Analysis: A Lifecycle-Oriented Perspective

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Abstract

Rapid progress in applying ai and data science to the field of health care enhanced the accuracy of medical image analysis in the early detection of diseases. However, the increased application of big medical image datasets poses significant ethical issues related to privacy, consent, ownership, and proper usage. The current methods have been addressing the issue in a fragmented manner, providing limited practical guidelines for implementation. In this regard, the present study is proposing a simplified lifecycle approach for the development of a new framework for the simplified ethical data collection framework (sedcf) for the application of medical image analysis. The study reveals that the integration of ethics at the data collection stage is crucial for transparency, eliminating ambiguity in the application of the data, and proper development of ai for the field of healthcare.

Keywords: Medical Image Analysis, Data Ethics, Responsible Ai, Data Collection, Healthcare Ai, Privacy, Consent.

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1. Introduction

Medical Image Analysis (MIA) is now a critical component of the modern healthcare system, mainly due to the development of artificial intelligence (AI), machine learning (ML), and data science. The role of computational approaches for the analysis of medical images such as X-rays, computed tomography (CT) scans, and magnetic resonance imaging (MRI) is now critical in the early detection of diseases and the overall well-being of patients. The development of deep learning algorithms has further increased the accuracy of the system, which again underlines the importance of Medical Image Analysis (MIA) (Chen et al., 2022; Chakraborty & Mali, 2023). At the same time, the efficiency of MIA is largely dependent on the presence of medical image datasets. Such datasets usually carry critical patient information. In this regard, the issue of privacy, along with informed consent, is a critical area of concern. However, the majority of the research has been focused on the enhancement of the efficiency of the analytical process (Almubarak, 2025; Phang et al. 2025). In contrast, the aspect of the integration of ethical factors during the course of the data collection process

has received less consideration. Such a consideration is critical since the decisions made during this period will affect the reliability of the subsequent processes. (Martin et al., 2022; Floridi et al., 2023).

The increasing adoption of AI systems in healthcare has also raised other challenges, such as the misuses of data, biases, and a lack of transparency and accountability. In many of these challenges, it has been argued that the root cause of the problems lies not with the AI systems themselves, but with the manner in which the data is collected and processed. This, therefore, necessitates not only the formulation of ethical guidelines but the development of structured approaches that consider ethical issues at every stage of the data life cycle (Jobin et al., 2019; Goktas & Grzybowski, 2025). This becomes extremely significant when dealing with the medical image analysis since it has a direct relation to the patient safety.

Secondly, there is an ever-increasing gap between the speed of technological development and the development of a set of appropriate ethical and regulatory responses (Floridi et al., 2023; UNESCO, 2024). The more advanced and sophisticated the MIA

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models become, the newer and more complex the models get, yet the appropriate set of measures, by which to guarantee the transparency and accountability of the whole system does not grow with the models. The ethical measures are mostly viewed as a mere compliance requirement.

The move towards precision medicine and personalized diagnostics has further fueled the demand for big and diverse medical image datasets. Such efforts usually require the engagement of various stakeholders, which is a complex issue. Inconsistencies in the management of the datasets will continue to exist if a proper approach is not adopted. Issues related to the ownership of the data, changes in the consenting environment, and the sharing of the data across borders require governance frameworks that are flexible yet sensitive to the context (Kalkman et al., 2023; Bartlett et al., 2024).

Under this context, the present study attempts to put forward a Simplified Ethical Data Collection Framework (SEDCF) for the purpose of medical image analysis. The framework is developed with the objective of providing a structured yet simple framework for the incorporation of ethical principles in the data collection process. The framework will allow the practitioners to address the pertinent ethical issues related to privacy, consent, data validity, and usage in a systematic manner. The incorporation of ethical principles in the early stages of the data handling process will help the development of trustworthy AI.

The rest of this paper is organized as follows. In Section 2, we discuss existing practices and their associated ethical concerns. In Section 3, we present our proposed SEDCF, including its theoretical underpinning and stage-wise development. In Section 4, we discuss some of its implications, and finally, in Section 5, we present our conclusions, including some of the limitations of our research and possible avenues for future research.

2. Current Practices and Emerging Ethical Concerns

The field of medical image analysis has witnessed significant growth with the increasing use of AI and deep learning in the field. The medical image datasets are generally collected from various hospitals, diagnostic centers, and online repositories. The datasets are used for various purposes, including disease classification, segmentation, prediction, etc. Large-scale datasets have been instrumental in developing models that can perform at a reasonable level. However, the

progress is largely dependent on the quality, variability, and ethics of the image datasets. In addition to the above, various studies have emphasized the fact that AI-based medical imaging poses a wide array of ethical issues at every stage, as discussed in the previous studies. (Khan et al., 2025; Chen et al., 2022)

One of the prominent issues that have been a concern in current practices is related to the absence of standardized ethical frameworks for managing consent as well as ensuring transparency in data usage. In many instances, it has been seen that data is collected through broadly defined consent agreements that are not fully understood by patients. This creates a sense of ambiguity with regards to autonomy as well as informed consent. Additionally, it has also been seen that patients are not aware of data reuse, data integration with other data sets, or data sharing with third parties, thereby creating ambiguity (Shabani & Marelli, 2024; Kalkman et al., 2023). This lack of governance, however, is crucial, considering that health data is such sensitive information.

The other important problem that exists in the datasets is the presence of bias and lack of representativeness of datasets. Bias can exist during data collection, during annotation, or differences in imaging protocol across institutes can lead to differences in models failing to generalize over other populations, and can lead to health inequalities. Work to date breaks these challenges into data bias, development bias and interaction bias in how AI systems are affected, and can have impact on the fairness of AI systems. This can be approached with increased focus on the diversity and representativeness of the datasets used.

There is also increasing concern regarding data security, accountability, and the regulation of medical imaging data. Although the medical imaging data is anonymized, there are still ways to identify the patient's records due to anatomical structure and information held in the image metadata. It highlights the need for a more holistic perspective of data ethics, considering all issues such as data privacy, transparency, and accountability. (Floridi et al., 2023; European Commission, 2024). Thus, all of these challenges indicate that the current methods are in a fragmented state and need a framework to bring more order to data collection in medical image analysis.

3. Proposed Simplified Ethical Data Collection Framework (SEDCF)

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This section will present the SEDCF, including its underlying theory, the underlying principles for its structure, and the five stages in which the SEDCF is implemented. The SEDCF is intended to be a lifecycle approach that is practical and oriented toward the field. Each stage in the data collection process is intended to have a corresponding set of ethical responsibilities. The SEDCF is based on the idea that the best approach to ethics is to incorporate them at every point in the data collection process rather than considering them as discrete points.

3.1 Theoretical Grounding

The SEDCF is based on two different yet complementary foundations: existing ethical principles in AI and healthcare, and existing lifecycle-based perspectives from data science practice. Ethical principles in AI systems have consistently highlighted the importance of privacy, fairness, accountability, transparency, and human oversight in AI systems (Floridi et al., 2023; OECD, 2023). Although these principles are commonly accepted, their abstract nature does not provide much guidance for data science practitioners working with medical image data in daily practice. Recent studies have shown that for ethical guidelines to be useful in practice, they must be mapped to stage-wise procedures in line with the activity stages of the AI project lifecycle (Gorelik et al., 2025).

The development of the SEDCF is further informed by a detailed analysis of the challenges associated with existing medical image data collection methodologies. Some of the challenges often cited in this regard include those associated with consent structures, a lack of control over how data will be used in a given context, problems of re-identification even after anonymization of medical images, and a general lack of control in data sharing. Overcoming such challenges, however, involves more than providing a few security measures; rather, what is needed are structures that are not only systematic but also dynamic. In medical image data collection methodologies, a good ethical framework has been observed to be achieved through inter-disciplinary collaboration, where multiple perspectives converge to develop an ethical framework, which in turn is refined through use rather than a pre-designed solution (Alelyani, 2025; Singh et al., 2025). A further dimension of a systematic approach to medical image data collection methodologies involves an emphasis on an ethical review process as a continuous

process rather than a one-time requirement (Barucci et al., 2026). In light of such a systematic approach to medical image data collection methodologies, the SEDCF proposes a sequential but iterative framework.

3.2 Design Principles

One of the key design considerations for the SEDCF is to ensure that it is simple to implement. As mentioned above, many existing frameworks for ethical decision-making are sound in theory but can be hard to implement in practice. In many healthcare research settings where time is of the essence, frameworks that are simple to implement will be more readily adopted since they can be integrated into existing procedures with minimal procedural burden (Nemteanu et al., 2025; Shrotriya et al., 2025). As such, the SEDCF is organized into five stages that are easily implemented, yet still retains the key aspects of responsible AI practice. At the same time, it is aligned with widely accepted global standards for ethical AI in healthcare, such as those outlined by UNESCO (2024), as well as regulatory advice published by the European Commission (2024) and OECD (2023). At the same time, it is intended that the SEDCF will be flexible enough to fit a range of different institutional settings, regulatory settings, and types of medical image data that are met with in practice. In this sense, the twin goals of simplicity and alignment are not necessarily at odds with one another (Barucci et al., 2026).

3.3 Framework Structure and Stages

The SEDCF is comprised of five stages that are both sequential and interrelated. Table 1 provides an overview of the stages of the SEDCF, together with the key activities within each stage, the corresponding key ethical focus areas, and the outputs for each stage. Figure 1 provides an overview of the entire SEDCF process flow with its feedback mechanism. The stages of the SEDCF start with the identification of the data source or nature. Next is the creation of consent structures that go beyond data subjects' consent. Third is data minimization to only the extent necessary for collection, with special emphasis on possible re-identification. Before any analytical work is done with the data, an ethical validation step is included to ensure that the data is aligned with its intended use or purpose and is within acceptable standards of fairness. Finally, there is the stage for controlled use or governance of the data. All these stages are connected with an iterative feedback loop.

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Table 1: Simplified Ethical Data Collection Framework (SEDCF) — Stage Overview

Stage	Key Activities	Ethical Focus	Output
1. Data Source Identification	Classify dataset as primary or secondary; verify source legitimacy and provenance	Provenance, ownership, legitimacy	Source audit record
2. Consent Structuring	Design dynamic, context-sensitive consent; ensure patients are fully informed of current and future data uses	Autonomy, informed decision-making	Consent protocol document
3. Data Minimization and Anonymization	Collect only data necessary for the stated purpose; apply de-identification; assess re-identification risk	Privacy, proportionality	Anonymized, minimized dataset
4. Ethical Validation	Evaluate dataset for bias, fairness, and alignment with intended analytical	Fairness, societal impact, transparency	Ethical validation report

Stage	Key Activities	Ethical Focus	Output
	purpose		
5. Controlled Usage and Governance	Define access controls, data-sharing terms, and retention policies; initiate review when dataset is reused	Accountability, stewardship	Governance policy; iterative review trigger

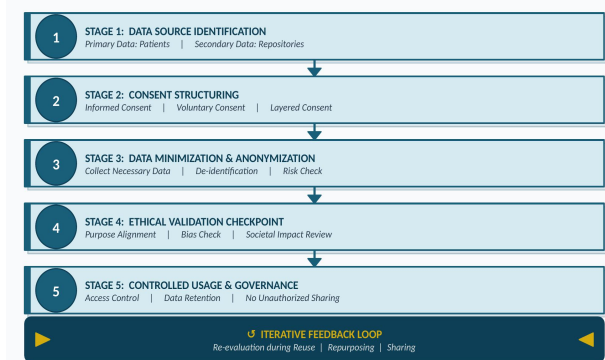


Figure 1 Simplified Ethical Data Collection Framework for Medical Image Analysis

Figure 1 shows the simplified ethical data collection framework for medical image analysis. In Figure 1, Stage 1 (Data Source Identification) primarily involves identifying the source of the data, which could be derived from patients directly (primary) or obtained from pre-existing sources (secondary). This distinction is important since it raises new ethical issues especially concerning the enforceability of the consent, and ownership. The consent structuring model (Stage 2) considers consent as an ongoing, evolving process not a bureaucratic form. The patient is not presumed to be only aware of the current need for data acquisition but aware of all imaginable future uses of that data. In Stage 3 (Data Minimisation & Anonymisation) proportionality is ensured in that only the required data is collected for the purposes of the analysis and appropriate anonymisation of the data is carried out. It needs to be

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thought about by practitioners if it is feasible to identify an individual from their image features or associated meta-data. In Stage 4, Ethical validation is a crucial step prior to conducting any analysis. At this stage the data set is analyzed for bias, assessed for fitness for the intended purpose and also for its implications for the society at large, particularly for the vulnerable sections of the society. The data set is supposed to be altered if it fails the given criteria for further use. In Stage 5, controlled usage and governance defines the rules for utilizing the data set. Usage is limited to authenticated users and a defined purpose of usage is maintained, dissemination of the data outside the defined boundaries are not permitted except through a formal agreement between the parties involved and data storage limitation is prescribed. All the above 5 stages are linked through an iterative feedback loop, where a change in the intended purpose or scope necessitates revisiting any of the above stages.

4. Discussion and Practical Implications

The SEDCF is a structured and yet, highly functional approach to incorporating ethics into the medical image data collection process. The framework links each phase of the data lifecycle to ethical issues. This is an important step since the risks that can be discovered in the early stages of the data lifecycle, before the data has even been collected, can often be resolved with very little effort. The risks discovered in the latter stages of the data lifecycle, however, can be huge and difficult to manage with large amounts of work required to alleviate them. Institutionally, it promotes patient trust through accountable data management; for data scientists and researchers it provides a clear approach to balance technological decision making with ethical considerations, reducing ambiguity; finally, the SEDCF implements recent evolving data governance principles in AI, embracing key aspects such as structuring of consent, minimization of data and control (OECD, 2023, UNESCO, 2024, European Commission, 2024) among the general recommended principles of data management.

The framework also takes into account the flexibility which is needed throughout all health care environments. In fact, medical image data is created within a broad range of institutional and regulatory settings, from highly regulated academic settings to smaller clinical settings where governance may not be as highly developed. The SEDCF is flexible enough to adapt to these different

settings since its components can be interpreted in context. For example, consent processes, anonymization processes, and data sharing processes can be tailored to fit the context of the settings where the data is being collected or used, yet still maintaining a similar structure for the governance process.

Dynamic consent models or data stewardship models, which are being emphasized in healthcare research settings, can be easily integrated into the consent structuring or governance stages of the SEDCF (Kalkman et al., 2023; European Commission, 2024). However, at the same time, there is a set of inherent trade-offs that have to be addressed when conducting ethical data collection. In most cases, there is a balance that has to be struck between utility and privacy. For instance, limiting the scope of collected data to only what is strictly necessary might limit the size and diversity of collected datasets, which might, in turn, impact model performance. Another consideration: in trying to attain representativeness through including groups with varied demographics, data acquisition cost might increase. These are not issues to be avoided: the whole point of building responsible AI is not to eliminate trade-offs, but to provide a process for dealing with them in a systematic rather than an arbitrary manner. Without an acknowledgment of such trade-offs, the system may lack credibility among researchers, practitioners and stakeholders. Another strength of the system is in the actual operationalization of responsible AI. Everyone agrees on the principles (fairness, accountability and transparency, etc.), but there are no easy ways to implement them. They require specific actions or outputs which is where the framework is helpful because it tries to establish links between principles and such actionable components relevant to the particular phase. The operationalization of ethical principles at the data collection level minimizes the risk of downstream problems during the development, evaluation, and deployment of AI models, where the cost of correction is high (Floridi et al., 2023; Jobin et al., 2019).

The framework is useful in the development of trustworthy AI in the healthcare sector based on consistent and verifiable practices. Finally, the framework will play a role in ensuring the sustainability of data-based healthcare research in the long term by reinforcing trust in the data. There have been several instances where data misuse has led to a

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decline in trust among patients, which has been a major impediment to healthcare research, irrespective of technological progress. The SEDCF will assist in reinforcing trust among patients by emphasizing transparency and ethical validity in data collection processes. With the emergence of technologies such as federated learning and differential privacy in healthcare-related artificial intelligence, it is believed that the importance of data collection processes will be further emphasized in the future (Bartlett et al., 2024; OECD, 2023).

5. Conclusion

This paper has presented a framework for ethical data collection in the field of medical image analysis, called the Simplified Ethical Data Collection Framework (SEDCF). The need for a framework that incorporates ethical considerations at the data collection stage was demonstrated through a discussion on the increasing reliance on data-driven approaches to artificial intelligence in healthcare. The SEDCF was presented as a five-step process that implements widely accepted ethical considerations. By adding the ethical aspects at the data collection phase, it was showed that an efficient medical image analysis system could be constructed.

The process of ethical data collection in health care goes beyond compliance with laws and regulation; it is the key step for developing trustworthy A.I systems for patients, healthcare providers and regulatory bodies. According to the SEDCF, there are essential aspects such as context-based consent, appropriate data collection, and ongoing ethical evaluation and accountable governance, which are crucial for this purpose. With the continued progress of medical imaging AI technology, it is believed that the significance of strengthening the process of ethical data collection would continue to rise. Such frameworks, like the SEDCF, are crucial for achieving a balance between ethical design and usability.

5.1 Contributions to Research and Practice

The study has two major contributions to make. From a research point of view, the study develops an ethical framework with a lifecycle approach that is specifically applicable to medical image data collection, which has received relatively less attention in the broader responsible AI literature. Most existing frameworks for healthcare-related AI applications have been found to be at an abstract level that prevents their direct applicability to data collection practices (Florida

et al., 2023; Jobin et al., 2019). The SEDCF addresses the above limitation of existing frameworks by linking existing ethical principles with data collection practices, consent construction, data minimization, validation, etc. The proposed approach is an extension of existing work related to lifecycle-based ethical governance for AI systems (Barucci et al., 2026; Gorelik et al., 2025).

Practically speaking, the framework will enable data scientists, healthcare experts, and research institutions to address the ethical issues they commonly face in a more structured fashion. By including the ethical validation step, the framework addresses the pressing issue of the early identification of bias and societal impacts before using the datasets for developing AI models, as emphasized in recent studies by Raji et al. (2021) and Kalkman et al. (2023). Furthermore, the framework will enable future research on the development of benchmarks for the automatic evaluation of the ethical compliance of AI models, the integration of the proposed approach in the development pipeline for AI models, and the creation of benchmarks for the development of ethically curated healthcare image datasets. By contributing to the growing body of research on the governance of AI systems, this study supports the emerging consensus on the critical importance of the data collection phase in the development of AI systems, where many critical issues related to the ethics of AI can be effectively addressed, as emphasized in recent studies by Goktas & Grzybowski (2025) and the European Commission (2024).

5.2 Limitations and Future Research

Some limitations of the study must be mentioned. Firstly, the SEDCF is not an empirically validated instrument as it is based on the synthesis of existing literature and conceptual analysis. Secondly, it has not been tested using user studies with data scientists or practitioners. Future work must be done to test the practical applicability of the framework in different settings, which would help identify any challenges with its implementation and its effect on compliance with ethical standards. It would also help refine the stages and outputs based on practical experience. Even though the SEDCF is designed specifically for medical image analysis; the approach might also be applicable to another related field in the health sector. Nonetheless, to extend the framework to other sectors of the health system like genomics, electronic health records and wearable sensor data, it

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might need some adjustments which would be sector-specific, according to the privacy and consent-related constraints. Thirdly, even though the five-stage framework structure is deliberately simplified, the actual usage of the framework could rely on the availability of resources for its usage, particularly for organizations that have had no prior experience in data ethical governance practices. Hence, for a future research work, it is essential to focus on developing resources to assist the implementation of this framework. Collaboration between AI researchers, clinical ethicists, regulators and patient organizations will also be crucial to assure that the framework is aligned with societal values as well as practical needs.

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