# Unraveling a Dilemma in Healthcare Projects: Is It About Quality Improvement or Research?

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## ABSTRACT

**Introduction:** in health sciences, distinguishing between research projects and quality management or improvement projects is a frequent challenge. Both approaches can share similar methodological tools, such as systematic data collection, statistical analysis, and results communication. This overlap generates conceptual and practical confusion, especially when improvement projects adopt designs typical of clinical research or seek academic dissemination. Clarifying these differences is fundamental to ensuring ethical and regulatory compliance.

**State of the art:** health research is defined by its objective of generating new and generalizable knowledge, requiring evaluation and approval by an ethics committee. In contrast, quality management or improvement projects are oriented toward optimizing processes, results, or efficiency within a specific institution, without the intention of extrapolating the findings. The literature indicates that confusion arises when improvement initiatives use rigorous research methodologies or when their results are presented for publication, blurring the boundaries between the two approaches.

**Conclusion:** the central element for differentiating between these two types of projects is their purpose. When the primary objective is to answer a scientific question with an impact beyond the local context, it is considered research. If the aim is to solve a specific operational problem, it falls under quality improvement. In ambiguous scenarios, consulting the ethics committee is recognized as a recommended practice that helps safeguard the ethical and regulatory integrity of projects.

**Keywords:** biomedical research, quality improvement, ethics committees, research, quality of health care, research, Argentina

**Desenredando un desafío ético en los proyectos de salud: ¿se trata de gestión/calidad o investigación?**

## RESUMEN

**Introducción:** en ciencias de la salud, la distinción entre proyectos de investigación y proyectos de gestión o mejora de la calidad constituye un desafío frecuente. Ambos enfoques pueden compartir herramientas metodológicas similares, como la recolección sistemática de datos, el análisis estadístico y la comunicación de resultados. Esta superposición genera confusión conceptual y práctica, especialmente

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Received: 09/25/2025 Accepted: 06/19/2026 | Published: 06/26/2026

DOI: http://doi.org/10.51987/Rev.Hosp.Ital.B.Aires.v46i2.1297

How to cite: Soli S, Appeceix JS, Senillosa M, Perman G, Grande Ratti MF. Untangling an Ethical Challenge in Healthcare Projects: Is It Quality Improvement or Research? Rev Hosp Ital B.Aires. 2026;46(2):e0001297.





ISSN (en línea) 2314-3312

cuando los proyectos de mejora adoptan diseños propios de la investigación clínica o buscan difusión académica. Clarificar estas diferencias resulta fundamental para garantizar el cumplimiento ético y normativo.

**Estado del arte:** la investigación en salud se define por su objetivo de generar conocimiento nuevo y generalizable, requiriendo evaluación y aprobación por un comité de ética. En contraste, los proyectos de gestión o mejora de la calidad se orientan a optimizar procesos, resultados o eficiencia dentro de una institución específica, sin intención de extrapolar los hallazgos. La literatura señala que la confusión surge cuando iniciativas de mejora utilizan metodologías rigurosas propias de la investigación, y/o cuando sus resultados se presentan para publicación, lo que difumina los límites entre ambos enfoques.

**Conclusión:** el elemento central para diferenciar ambos tipos de proyectos es el propósito. Cuando el objetivo principal es responder una pregunta científica con impacto más allá del entorno local, se trata de investigación. Si la finalidad es resolver un problema operativo específico, corresponde a mejora de la calidad. Ante escenarios ambiguos, la consulta al comité de ética se reconoce como una práctica recomendada que contribuye a resguardar la integridad ética y regulatoria de los proyectos.

**Palabras clave:** investigación biomédica, mejoramiento de la calidad, comités de ética en investigación, investigación, calidad de la atención de salud, Argentina.

## INTRODUCTION

The distinction between a clinical research project and the evaluation of a health management or quality improvement project may seem subtle, but it is important to differentiate between them from both an ethical and a regulatory perspective.[1] This article aims to reflect on their specific features and provide tools for their appropriate classification, analyzing and contextualizing them within the Argentine regulatory, ethical, and institutional framework, where practical challenges remain regarding their operational distinction and implementation.

## STATE OF THE ART

### A frequent dilemma in practice

Twenty years ago, Lynn addressed the tension between what is considered quality improvement (QI) and what is defined as human subjects research, focusing on how ethical regulations apply in each context.[2] The author suggested several key factors that serve as guiding criteria: the purpose of the project, rapid feedback to the system, participants and risks, project design, intent to publish or communicate findings, source of funding, operational definitions of "human subjects research" (e.g., whether the interventions are part of usual practice or not; whether the proposed actions will be implemented temporarily or permanently, among others), and regulatory aspects. Lynn already emphasized that the main purpose of this distinction is to protect *participants* (e.g., patients, family members, caregivers, professionals, teachers, students) and the system, without hindering the implementation of necessary improvements.[2] For example, a health program is considered a management activity when data are used to monitor coverage, performance, efficiency, or local impact, although it may include research components (e.g., if publication is intended).

When there is uncertainty about the appropriate classification of a project, some level of ethical review should be undertaken, even if only through a simplified process. In this regard, Patel et al. examined in 2013 how ethics committee review (*Institutional Review Board [IRB*] review) varied across multiple sites during the implementation of a quality improvement project.[3] They measured the time to submission, approval, and study initiation, finding that the greatest delay occurred before protocol submission (45 ± 32 days), whereas approval required an average of 14 ± 6 days, with 80% of projects approved through expedited review.[3]

Notably, most institutions required documented informed consent from participants,[3] although there was considerable variability in review criteria because these projects were considered to involve "minimal risk." According to the *Belmont Report*,[4] U.S. regulations (e.g., 45 CFR 46),[5] and the *Council for International Organizations of Medical Sciences* (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans,[6] *risk is considered minimal when the probability and magnitude of anticipated harm or discomfort are no greater than those ordinarily encountered in daily life or during routine physical or psychological examinations.*

Practical examples of activities generally considered to involve minimal or low risk include observation of routine clinical practice (without modifying patient management or treatment for research purposes), retrospective review of medical records (provided that the confidentiality of personal data is ensured), anonymous surveys or interviews that do not include sensitive questions,[7] and organizational interventions (e.g., structural changes to clinical protocols, institutional policies, or certain healthcare programs).[8]

### Risk Classification of Health Research in Argentina

The regulatory framework of the Province of Buenos Aires (which may vary slightly across jurisdictions) defines the following categories:

• "No-risk" research includes: (a) studies that use publicly available data; (b) studies conducted with data or biological samples stored in healthcare institutions in such a way that the identity of the individuals cannot be determined; and (c) methodologically descriptive, registry-based, epidemiological, or cross-sectional and longitudinal observational studies, provided that participants cannot be identified.[9] These projects do not require specific protective measures. According to Resolution No. 1480 of the Argentine Ministry of Health, they pose no risk and therefore do not require any oversight mechanism.9

• "Minimal-risk" research includes studies classified as such by the Joint Commission on Health Research (*Comisión Conjunta de Investigación en Salud*), pursuant to Article 6(b) of Law No. 11,044.[9] These include: a) Cross-sectional and longitudinal studies involving identifiable data, identifiable biological samples, or vulnerable populations (defined on the basis of age, health status, or socioeconomic condition), where risk is assessed from physical, psychological, emotional, or socioeconomic perspectives. b) Analytical studies using records or information related to participants' previous experiences, in which the data remain identifiable and linked to the study participants. c) Observational studies involving surveys or interviews: the risk lies in the handling of data, compliance with confidentiality requirements, and the management of sensitive personal information, as established by Personal Data Protection Law No. 25,326; d) Interventional studies involving routine diagnostic procedures or standard treatments: although these procedures carry only the risks associated with usual clinical practice, they are performed for research purposes. e) Observational studies in which participants can be identified from the collected data, among others.

The regulatory framework of the Government of the City of Buenos Aires establishes that *health research may involve different levels of risk for participants depending on the specific characteristics of each study* and therefore requires oversight and monitoring by Research Ethics Committees (RECs).[10] It defines the following categories:[10]

• No-risk research: studies in which no intentional modification or intervention is made on participants' biological, psychological, or social variables, and in which participants cannot be identified. Examples include studies that do not involve human participants; studies using data or biological samples stored in healthcare institutions in such a way that the identity of the individuals cannot be determined (e.g., retrospective reviews of de-identified medical records or analyses of anonymized biological samples); and studies using questionnaires or interviews that do not collect information enabling participant identification (personal data) or address sensitive topics.

• Minimal-risk research: studies in which the risks are similar to or no greater than those encountered in routine medical practice. Risks may be associated with participants' exposure to measurements or procedures that, although part of standard clinical care, are performed more frequently or exclusively for the purposes of the proposed research. Privacy, confidentiality, and data security must also be ensured during data collection, transmission to other centers, and the development of shared databases, particularly when information is transmitted electronically.

At the national level, Resolution No. 1480/10 of the Argentine Ministry of Health[11] establishes the following exceptions that do not require review by a Research Ethics Committee (REC):

a. Research that does not involve human participants or that uses publicly available information, provided that individuals cannot be identified in any way.

b. Studies limited to the evaluation of health systems, official public health programs, or epidemiological surveillance activities, provided that there is no possibility of identifying individual participants.

## Comparative Analysis

Although the regulatory frameworks described above share general criteria for classifying research risk, they differ in the level of detail provided in their definitions, the oversight mechanisms they require, and the exceptions they establish for ethical review. These differences may lead to variability in the interpretation and classification of similar projects across jurisdictions, potentially affecting review timelines and increasing the administrative burden for investigators and institutions, particularly in multicenter studies. From an operational and logistical perspective, the adoption of harmonized and clearly defined criteria would promote a more consistent application of regulatory requirements, thereby streamlining the ethics review process without compromising the protection of research participants.

Despite substantial conceptual agreement regarding which studies may be considered exempt from ethics review, which qualify as minimal-risk research, and which oversight mechanisms are required in each jurisdiction, considerable heterogeneity persists in ethics review processes. Harmonizing criteria across jurisdictions therefore remains an important challenge for improving regulatory efficiency and enhancing the predictability of review procedures. In line with this objective, Decree No. 893/2025 established the National Bioethics Commission within the Argentine Ministry of Health and strengthened federal coordination in matters related to research ethics and the accreditation of Research Ethics Committees (RECs). We believe that this regulation provides important context for understanding the recent evolution of Argentina's national regulatory framework governing the ethical review of health-related projects. It is also expected to centralize the management of ethics review processes (e.g., by preventing regulatory inconsistencies and overlaps, strengthening coordination, reducing administrative burden and review times, optimizing resource allocation, and providing greater consistency, predictability, legal certainty, and effectiveness in the application of ethical standards).

## Research or Quality Improvement/Management? Real-World Examples and Letters of Ethical Non-Objection

Example A (Table 1) illustrates how the boundary –the "gray area" of uncertainty– between quality improvement

and research may become blurred in practice. Although the project originated as an intervention aimed at improving healthcare processes, the systematic collection of data and the intention to disseminate the findings beyond the institution introduce characteristics typically associated with health research. This broader scope has ethical and regulatory implications, particularly regarding review by a Research Ethics Committee (REC), the protection of personal data, and, where appropriate, exemption from informed consent or formal ethics approval.[12] Because the editorial policies of scientific journals generally require evidence of ethics approval in accordance with international standards (Figure 1), investigators may request a waiver of ethical approval. Likewise, in certain minimal-risk research settings, a waiver of informed consent may also be appropriate.

Example B (Table 1) illustrates another common situation in which a project initially conceived as a management report or quality improvement initiative evolves to include objectives related to the generation and dissemination of knowledge beyond the institutional setting.[13] Such cases highlight the need for review mechanisms proportionate to the level of risk, including expedited review or simplified procedures by Research Ethics Committees (RECs), particularly when the anticipated risks do not exceed minimal risk.[14]

In addition, some institutions have established alternative pathways for evaluating quality improvement projects and issuing determinations that formal ethics approval is not required. As a real-world example, the Ethics and Research Protocol Committee (Comité de Ética y Protocolos de Investigación, CEPI) of the

**Table 1.** From Theory to Practice: Real-World Examples of Uncertainty

| | |
|---|---|
| Case A | At a meeting, a department head proposes a new care model that he will call the Integrated Practice Unit for the care of people with lung cancer, aligned with the institutional strategic framework and value-based medicine. "Our goal will be to optimize care through a multidisciplinary approach that improves accessibility, standardizes clinical management, and ensures high-quality care with efficient use of resources," he says enthusiastically. A fellowship trainee asks if they should submit the project to the Ethics Committee. "No, this is just an internal improvement," he replies. Months later, the team decides to write an article to publish the preliminary results of the pilot study. But when they submit it for peer review to a scientific journal, they are asked for ethical approval, since the work "appears to be research." |
| Case B | On a Monday morning, during an Academic Session of the Internal Medicine Research Area, the evaluation report received from the Research Ethics Committee (REC) was discussed. The reviewer asked:<br>"In what context is this study being conducted? Please clarify whether it involves the evaluation of institutional quality improvement processes. If so, the protocol should describe the measures that will be taken if the intervention yields unsatisfactory results."<br>The protocol, CEPI#7596, is entitled "*Rapid Comprehensive Geriatric Assessment Unit in the Emergency Department for Health Plan Members Aged ≥80 Years.*" The study protocol explains that the organizational change had already been implemented (i.e., it is retrospective), and that data collection will rely on secondary retrospective data. As such, it could reasonably be considered a management experience report.[13]<br>However, following a discussion among the investigators, we concluded that the project not only aims to document outcomes and share lessons learned and reflections, but also qualifies as research because:<br>a) Its purpose extends beyond internal quality improvement and seeks to generate generalizable knowledge (i.e., the intention is to disseminate the findings beyond our institution).<br>b) It is not limited to describing the professional experience from the perspective of the management team, but also involves the collection of patients' clinical data.<br>c) Although the institutional management dashboard will serve as the primary data source, additional data will also be requested from the Department of Information Management for Research to obtain other variables (e.g., outcomes related to post-consultation follow-up). |

**Protocol Version 1 – Date 07/25/2022**

## Ethical Considerations

**This project was designed as a purely observational study of routine patient care, without any intervention introduced specifically for the purposes of this protocol.**
**The coordinators of the Lung Integrated Practice Unit (IPU) will serve as custodians of the server and database and will be responsible for their maintenance, technical support, updating, and expansion should new variables or projects be incorporated into the registry.**
According to **Resolution No. 1480/2011 of the Argentine Ministry of Health, this project could be considered exempt from review by a Research Ethics Committee (REC), as evaluations of healthcare programs or services constitute an exception:**
***"At times, it may be difficult to distinguish whether a specific project constitutes research or the evaluation of a health program or healthcare service. The defining characteristic of research is its purpose of producing new and generalizable knowledge. In contrast, an evaluation seeks only to identify and describe characteristics or findings pertaining to a single individual, a group of individuals, or a specific program. The evaluation of an official health program or healthcare service conducted by the program's own personnel or by institutional staff should be regarded as an activity necessary to ensure the effectiveness and safety of a facility or procedure, always with the aim of benefiting the individuals receiving care."***
**This particular project (i.e., the IPU program) collects clinical information related to healthcare delivery within the framework of a new model of care. However, given the uncertainty regarding its proper classification, we decided to submit the protocol to the Research Ethics Committee (REC) for determination and, if deemed appropriate, approval.**

**Figure 1.** Ethical considerations paragraph from protocols CEPI#6486 and PRIISA#7753.

Hospital Italiano accepts submissions by e-mail, in summary format, for publications that "exclusively report interventions that have already been completed, whose sole purpose is to communicate the results of a quality improvement process, and that do not involve the collection of new data." When appropriate, the committee issues a *letter of no ethical objection*.

Finally, most funding opportunities for health-related projects (e.g., grants or research awards) require prior ethics approval or, at a minimum, documentation that the project has been submitted for review by a Research Ethics Committee (REC). This requirement applies to both public and private funding sources, whether national or international, and is particularly stringent when a project involves human participants, uses personal or clinical data, includes interventions or diagnostic procedures, or is submitted as scientific or academic research.

It is important to emphasize that the requirement for review by a Research Ethics Committee and the requirement to obtain informed consent are often confused, although they are related but independent ethical requirements.[15] For example, a waiver of informed consent may be appropriate when a study is limited to collecting information from medical records or administering a low-risk questionnaire or an anonymous survey.[15]

### When the Methods Are Similar but the Purpose Is Not

Health Services Research (HSR) is a field that examines how healthcare services are organized, managed, financed, and delivered, and how these factors influence health outcomes, access to care, efficiency, equity, and quality of care.[16] Such evaluations are essential for understanding and improving the performance of healthcare systems by examining organizational processes, resource utilization, and the impact of administrative decisions on the quality of care.

It represents a comprehensive, structured, and measurable approach to organizational management that applies both qualitative and quantitative methods to improve the effectiveness, efficiency, and adaptability of all organizational processes.[17] It typically emphasizes a person-centered approach, in which patient satisfaction is the primary objective.[17] Its purpose is to generate actionable knowledge that supports safer and more efficient healthcare,[1] and it may draw on a variety of data sources, including medical records, patient surveys, and administrative databases. Its primary aim is to provide evidence that informs administrative decision-making, strengthens institutional policies, and supports continuous quality improvement.

Although Health Services Research and clinical research share methodological features such as systematic data collection and analysis, they differ in several important

respects. Table 2 and Figure 2 summarize the defining characteristics of each approach, facilitating their critical distinction. Differentiating between these types of initiatives is essential for determining the appropriate scope of ethics review and the responsibilities of investigators.

## CONCLUSIONS

The boundaries between health research and quality improvement are not always clear, particularly when projects employ similar methodologies, involve the systematic collection of data, or are intended for dissemination beyond the local setting. Although the primary purpose of a project remains the key criterion for its classification, this determination should also take into account the study context, the level of risk involved, the anticipated scope of the findings, and the applicable regulatory framework.

Primary responsibility rests with the organizations involved rather than with Research Ethics Committees (RECs).[18] From a regulatory perspective, however, responsibility is shared and complementary because: (a) institutions are responsible for promoting good practices, data governance, training, and oversight mechanisms; (b) investigators are responsible for the design and conduct of the project; and (c) RECs are responsible for conducting an independent ethical review, when applicable, and determining whether a project requires full review, expedited review, or exemption.

In both research and quality improvement initiatives, respect for autonomy, privacy, and the confidentiality of information constitutes a fundamental ethical principle. In Health Services Research, the primary ethical consideration concerns the handling of health

**Table 2.** Distinguishing Characteristics of Health Research and Healthcare Management (or Quality Improvement) Projects

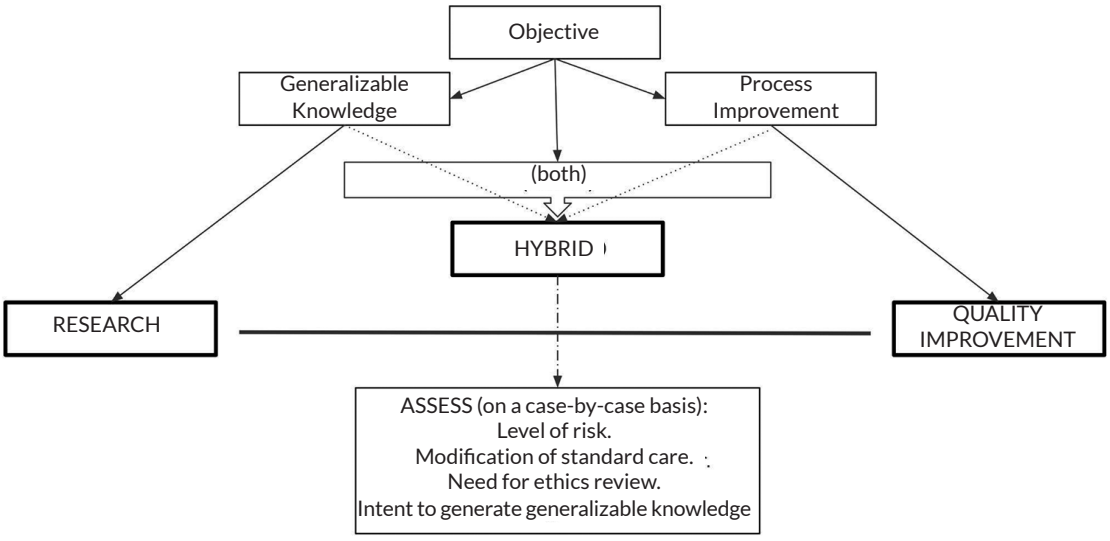
| | Health Research Project | Healthcare Quality Improvement (or Healthcare Management) Project) |
|---|---|---|
| Primary objective | To generate knowledge that contributes to answering scientific or professional questions and may potentially be applicable to other settings. | To improve processes, outcomes, or organizational performance within a specific institution or healthcare system. |
| Expected Scope of the Findings | Often intended to generate transferable or generalizable knowledge. | Primarily intended to address local problems, although the findings may also be of interest to other institutions. |
| Hypothesis or Research Question | Typically present (explicitly stated). | Not always required; typically focused on improvement objectives. |
| Risks to Participants | Varies depending on the study design and procedures involved. | Typically minimal or no greater than the risks associated with routine care (as it is generally based on the use of routinely collected healthcare data or on the implementation of evidence-based improvements that have already been shown to be safe and effective), although each project should be evaluated on a case-by-case basis. |
| Ethics Review | Almost always required, although the requirement depends on the level of risk and the applicable regulations. | Conditional (e.g., if publication is intended). |
| Modification of Standard Care or Relationship to Routine Clinical Practice | May involve observation of routine clinical practice or, frequently, additional protocol-defined interventions. | Rarely, as these projects typically implement changes intended to optimize clinical care or healthcare management processes within routine clinical practice. |

Internal validity is not exclusive to quality improvement projects.

External validity is not exclusive to research.

Both types of projects may seek to achieve both forms of validity to varying degrees.

Source: Prepared by the authors.




Source: Prepared by the authors

**Figure 2.** Conceptual framework to guide and facilitate the critical classification of project types

information. Protecting confidentiality and personal data is therefore essential, requiring that records be anonymized and access restricted exclusively to authorized personnel.

Quality improvement and management projects should be conducted in accordance with the institutional and regulatory context in which they are implemented (e.g., review by a Research Ethics Committee may even be mandatory). Even so, project leaders have a professional and ethical duty to act with integrity, regardless of whether the project has undergone ethics review.

Ambiguous situations may arise, and some projects may even combine elements of both research and quality improvement. Accordingly, we offer the following practical recommendations:

* If the intention is to publish the findings and generalize the results, the project should probably be treated as research, since many scientific journals require ethics approval as part of their editorial policies.

* If external funding is sought, the project will likely require ethics review and/or approval, regardless of whether it is classified as research, quality improvement, or management.

* Funding agencies require evidence of ethics review when a project involves human participants, clinical data, medical records, or biological samples. This requirement is intended to ensure the adequate protection of participants, the responsible handling of information, and compliance with applicable regulations.

* When in doubt, consultation with a Research Ethics Committee is considered good practice to ensure compliance with ethical and regulatory requirements. The need for a waiver of informed consent does not justify the absence of ethics review, and conversely, ethics review does not necessarily imply that informed consent is required.

**Author Contributions:** Conceptualization, Data curation, Formal analysis, Investigation, Software, Methodology, Project administration, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing: SS, JSA, MS, GP, MFGR.

**Conflicts of Interest:** The authors declare that they have no conflicts of interest related to the content of this work.

**Funding:** The authors declare that no external funding was received for this study.

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