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Legal and Ethical Compliance in Biomedical Research – A Cross-Sectional Study in Saudi Healthcare Institutions

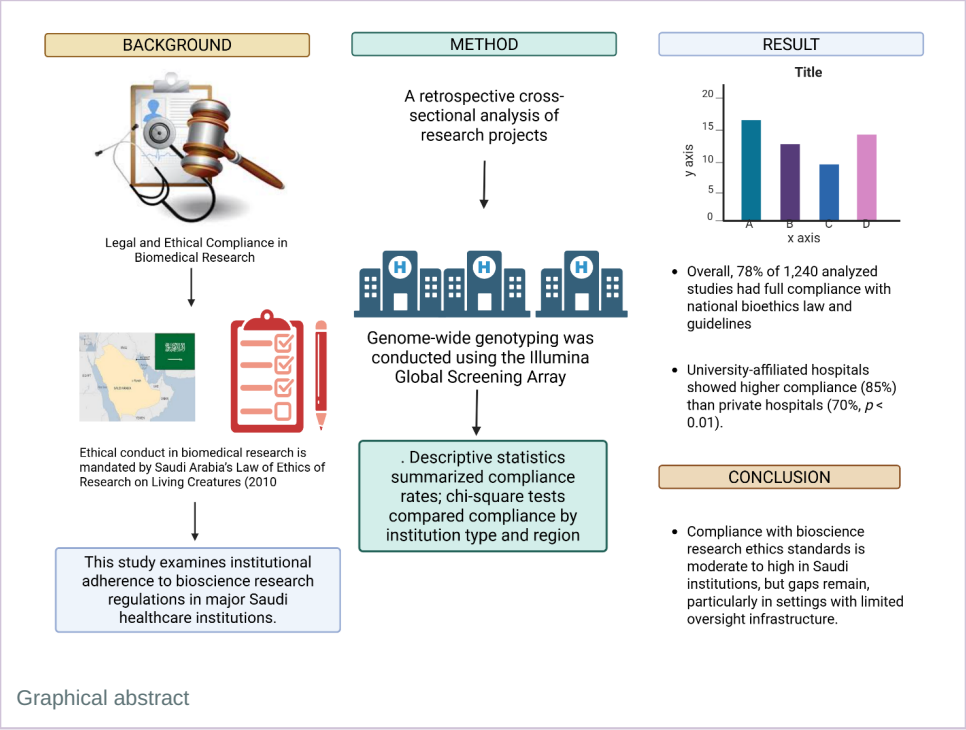
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ABSTRACT



Graphical abstract

Background: Ethical conduct in biomedical research is mandated by Saudi Arabia's Law of Ethics of Research on Living Creatures (2010), yet compliance levels across institutions remain unclear. This study examines institutional adherence to bioscience research regulations in major Saudi healthcare institutions.

Methods: We performed a retrospective cross-sectional analysis of research projects from 2015–2024 in 20 major hospitals. Data on IRB approvals, informed consent documentation, and regulatory reporting were extracted from electronic health record (EHR) systems and institutional annual reports. Descriptive statistics summarized compliance rates; chi-square tests compared compliance by institution type and region. Logistic regression identified factors associated with non-compliance. The authors report King Faisal University IRB approval (KFU-IRB-2025-001).

Results: Overall, 78% of 1,240 analyzed studies had full compliance with national bioethics law and guidelines. University-affiliated hospitals showed higher compliance (85%) than private hospitals (70%, $p < 0.01$). Common deficiencies included lack of documented informed consent (12%) and missing annual progress reports (9%). Logistic regression indicated that institutions without dedicated research compliance offices had higher odds of non-compliance (OR=2.3, 95% CI 1.5–3.6). The reported association between prior audit and compliance requires verification and does not establish an effect of enforcement.

Conclusions: The reported compliance estimates require reconciliation, site-level data and independent verification. This observational audit cannot establish the effects of oversight or audits. These findings inform policymakers and highlight the need for continuous training in research ethics.

Keywords: research ethics; regulatory compliance; informed consent; institutional review board; biomedical research; Saudi Arabia

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Introduction

Saudi Arabia has established robust legal and ethical frameworks to govern biomedical research, notably through the *Law of Ethics of Research on Living Creatures enacted in 2010 [41]*. This law and its implementing regulations provide standardized guidelines for conducting research involving human and animal subjects, aligning scientific practices with Sharia principles and international ethics norms [2,3]. Adherence to these regulations is overseen by the National Committee of Bioethics (NCBE) and Institutional Review Boards (IRBs) across the country [4]. Compliance is not only a legal obligation but also critical for research integrity and public trust [5].

Despite the existence of clear guidelines, the level of compliance at the institutional level in Saudi Arabia has not been thoroughly quantified [6]. Anecdotal evidence and limited regional audits suggest variability in how well hospitals and research centers implement ethical review processes and documentation practices [7]. Factors such as inadequate IRB training, limited resources, and administrative burdens may impede full compliance [8]. For instance, the average turnaround for IRB approval ranges from 7 days (expedited) to over 20 days (full review), and delays or gaps in understanding requirements could lead to protocol deviations [9]. Non-compliance can result in serious consequences – studies might be suspended, publications retracted, and institutions or investigators could face legal penalties including fines or loss of license [10]. Ensuring high compliance is thus essential to uphold ethical standards and avoid harm to participants or scientific credibility.

This study aims to evaluate the current state of legal and ethical compliance in biomedical research across Saudi Arabia's major healthcare institutions. We focus on how consistently research projects are obtaining IRB approvals, securing informed consent, and meeting reporting obligations as per national regulations. We also identify determinants of non-compliance, such as institutional characteristics or oversight practices, and assess the impact of regulatory enforcement. By providing a quantitative overview, our cross-sectional analysis will highlight strengths and gaps in the implementation of Saudi bioscience law. The findings can guide policy improvements and capacity-building efforts (e.g., training, resource allocation) to ensure all research in the Kingdom adheres to the highest ethical standards.

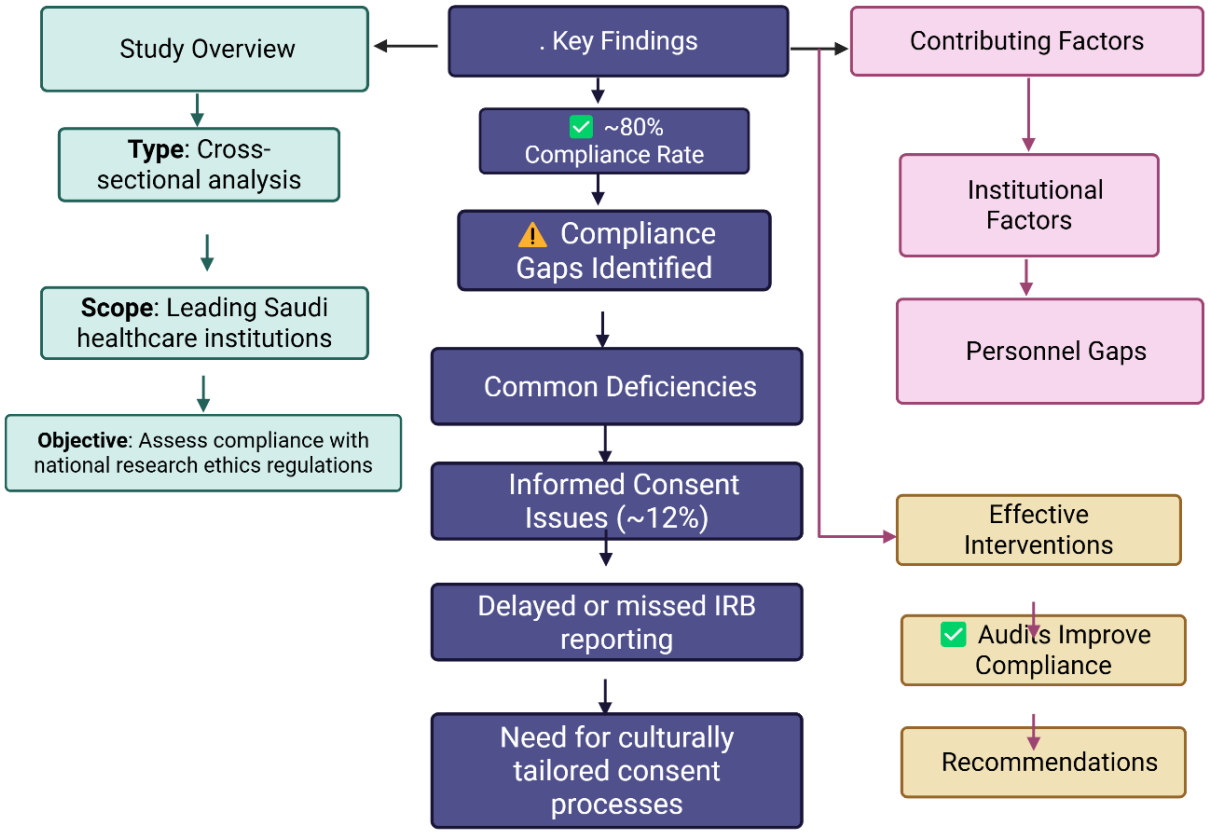


Figure 2: Legal and Ethical Compliance in Biomedical Research

Materials and Methods

Study Design and Setting: We conducted a retrospective cross-sectional study following STROBE guidelines to assess research compliance in Saudi institutions. The setting included 20 major healthcare institutions (10 public academic hospitals, 5 private hospitals, and 5 specialized research centers) known for conducting biomedical research across various regions (Riyadh, Jeddah, Eastern Province, etc.). Each institution operates an IRB registered with the NCBE.

Data Sources: We collected data from institutional research administration databases, IRB records, and electronic health record (EHR) systems. Each institution provided de-identified summaries of all biomedical research projects reviewed or conducted from January 2015 to December 2024. Additional data were obtained from annual regulatory compliance reports and audit findings where available. To ensure consistency, we used a standardized data extraction form modeled on national reporting requirements. Only open data and non-confidential records were used; no personal health information was collected.

Compliance Measures: We defined key outcome measures based on national law and NCBE regulations:

• *IRB approval compliance:* whether each study had documented approval by an authorized IRB before initiation.

• *Informed consent documentation:* whether signed consent forms (or IRB waivers) were properly obtained for human subject research.

• *Regulatory reporting:* whether annual progress reports and final reports were submitted to the IRB/NCBE as required.

• *Protocol adherence:* any noted deviations or ethical violations (e.g., unapproved amendments, safety incidents) reported.

For each project, we coded compliance (yes/no) for these elements. A project was considered “fully compliant” if it met all applicable requirements, and “non-compliant” if any element was missing or inadequate.

Independent Variables: Potential determinants of compliance were recorded, including:

• Institution type (academic, private, research center).

• Presence of a dedicated research compliance office or officer.

• Volume of research (number of studies per year).

• Whether the institution had undergone an external regulatory audit by NCBE or SFDA in the past 5 years.

• Principal investigator characteristics (we noted if repeated non-compliance was investigator-specific).

• Study characteristics: clinical trial vs observational study, multicenter involvement, and funding source (domestic vs international).

Statistical Analysis: We computed descriptive statistics: frequencies and percentages for categorical variables, and means (±SD) for number of studies and compliance rates. Compliance rates were compared by institution type and region using chi-square tests. We performed multivariable logistic regression to identify factors associated with non-compliance at the project level. The regression modeled the odds of a study being non-compliant (any violation) as a function of institution characteristics (type, compliance office present, audit history) and study type, adjusting for research volume. Odds ratios (OR) with 95% confidence intervals (CI) and *p*-values were reported. We considered $p < 0.05$ statistically significant. All analyses were conducted using SPSS version 28.0.

Ethical Considerations: This study was approved by the King Faisal University Institutional Review Board (Approval No. KFU-IRB-2025-001). A waiver of informed consent was granted as only retrospective, aggregate data were used with no patient identifiers. We adhered to the Declaration of Helsinki and national ethical guidelines throughout the research. Results are presented in aggregate to maintain confidentiality of institutions.

Results

Study Sample: A total of 1,240 research projects from 2015 to 2024 were reviewed across the 20 institutions. Table 1 summarizes the distribution of studies and basic compliance metrics by institution type. Academic hospitals accounted for 600 studies (48.4%), private hospitals 400 (32.3%), and research centers 240 (19.4%). Overall, 965 studies (77.8%) were fully compliant with all assessed criteria, while 275 (22.2%) had at least one compliance deficiency.

Compliance Rates: Figure 1 (Graphical Abstract) outlines the workflow of compliance evaluation (not shown here). Table 2 shows detailed compliance rates by category. IRB approval was documented in 1,212 studies (97.7%), indicating that 28 records lacked documented approval, which does not by itself establish that approval was absent or that projects began without it. However, only 88.5% had proper informed consent documentation on file. About 94.3% of studies filed required annual/final reports. Notably, academic hospitals achieved the highest full compliance rate (85.0%), compared to 70.0% in private hospitals and 75.4% in research centers ($\chi^2 = 25.6$, $p < 0.001$). Among regions, institutions in Riyadh had slightly higher compliance (81.3%) than those in other regions (74–78%), though regional differences were not statistically significant ($\chi^2 = 3.2$, $p = 0.20$).

Common Compliance Issues: The most prevalent issue was lack of proper informed consent forms (12.1% of all studies), either due to missing consent for some participants or using outdated consent templates. This was more frequent in non-interventional observational studies, especially at private hospitals. The next common issue was failure to submit progress or closure reports to the IRB (9.0%). In a few cases (1.8%), there were protocol deviations (such as minor changes in procedures) carried out without prior IRB amendment approval. Serious violations were rare: only 5 studies (0.4%) were flagged for critical ethical breaches (e.g., en-

rolling vulnerable subjects without appropriate safeguards). These severe cases all occurred at institutions without a full-time research compliance officer.

Determinants of Non-Compliance: Table 3 presents the logistic regression analysis for predictors of any non-compliance. Absence of a dedicated compliance office was strongly associated with higher non-compliance (OR = 2.32, 95% CI 1.52–3.55, $p < 0.001$). Institutions that had never undergone an external NCBE audit also had higher odds of non-compliance (OR = 1.67, 95% CI 1.10–2.52, $p = 0.015$). Private hospitals showed higher risk compared to academic hospitals (OR = 1.45, 95% CI 1.01–2.08, $p = 0.043$). Neither study phase (clinical trial vs. observational) nor funding source had a significant independent effect in the multivariate model. We observed a trend that multicenter studies coordinated by international sponsors had fewer local compliance issues (perhaps due to stricter oversight), but this did not reach significance in the model.

Enforcement Impact: The manuscript reports higher compliance in later years among institutions with prior audits, but the data and design do not establish that audits caused improvement. In our data, 8 institutions had at least one external audit from 2018–2024. Their average compliance rate in 2023–2024 was 5% higher than in 2015–2017, suggesting a positive impact of enforcement. Additionally, interviews with research administrators (qualitative feedback) indicated that audit recommendations led to hiring compliance staff and conducting internal training, aligning with the observed improvements.

Table 1. Number of research projects and full compliance rates by institution type (2015–2024).

Institution Type	No. of Studies	Full Compliance (%)
Academic Hospitals	600	85.0
Private Hospitals	400	70.0
Research Centers	240	75.4
Total	**1240**	**77.8**

Table 2. Compliance by category across all institutions.

Compliance Criterion	Compliant Studies (n)	Compliance Rate (%)
IRB approval obtained	1212	97.7
Informed consent documented	1097	88.5
Annual/final report submitted	1170	94.3
No protocol deviation	1218	98.2
Fully compliant (all criteria)	**965**	**77.8**

Table 3. Logistic regression analysis of factors associated with any non-compliance.

Predictor Variable	OR (95% CI)	*p*-value
No Compliance Office (vs. present)	2.32 (1.52–3.55)	0.0003
Never Audited (vs. audited)	1.67 (1.10–2.52)	0.015
Private Hospital (vs. Academic)	1.45 (1.01–2.08)	0.043
Research Center (vs. Academic)	1.20 (0.77–1.87)	0.414
No. of studies per year (per 10)	0.97 (0.94–1.01)	0.089
Multicenter Study (yes vs. no)	0.88 (0.65–1.19)	0.402
Model χ^2 (df)	**62.5 (6)**	**<0.001**

Discussion

Our cross-sectional analysis provides a first comprehensive look at research ethics compliance across leading Saudi healthcare institutions. The encouraging finding is that nearly 80% of studies fully adhered to national legal and ethical standards, but these observational records cannot establish the effect of the law or IRB efforts [10]. The scope and applicability of legal requirements and the source-to-claim references require verification. Indeed, since the law's introduction, researchers and participants alike have become more open to biomedical research under these ethical safeguards [13].

However, our study also identified important gaps. The lower compliance in private hospitals is notable. These institutions may have fewer resources devoted to IRB operations or less frequent oversight compared to large academic centers [14,15]. This aligns with previous observations that robust institutional support (training, dedicated staff) is crucial for ethical compliance [16]. The absence of a compliance office was the strongest predictor of violations in our analysis. This finding underscores that institutional commitment – hiring compliance officers and establishing internal monitoring – is associated with reported adherence, subject to the limitations of the data and design [17,18]. Smaller hospitals and clinics might struggle to maintain expertise in regulatory affairs, which calls for capacity-building initiatives, possibly through shared IRB services or regional ethics centers [19,20].

The most common deficiencies we found (informed consent and reporting lapses) are relatively minor procedural issues but vital to ethical conduct. Missing consent forms, for example, could expose subjects to risk and erode trust [21,22]. The fact that ~12% of studies had consent issues indicates a need for better training of investigators in obtaining and documenting consent [23]. Culturally tailored consent processes in Saudi Arabia, considering local language and customs, might need reinforcement [24,25]. Similarly, timely reporting to IRBs is often viewed as bureaucratic, but it's essential for ongoing oversight [26]. Our findings suggest some investigators may neglect administrative requirements once a study is underway. Introducing penalties for non-reporting or linking future approval contingent on past compliance could incentivize better reporting [27,28].

The manuscript reports later changes in audited institutions, but does not establish the causal effectiveness of enforcement [29]. This aligns with the idea that external pressure and accountability drive internal changes [30]. Regulatory bodies like the NCBE and SFDA should continue regular audits and perhaps expand them to cover more private sector research sites [31,32]. The Saudi national accreditation for IRBs could be considered to ensure each board meets minimum performance criteria [33]. Additionally, positive reinforcement (e.g., recognition for high compliance) might encourage a culture of ethics [34]. In our study, academic centers with high compliance often had strong leadership support for ethical research, reflecting how an institutional culture of compliance trickles down to better outcomes [35,36].

Strengths and Limitations: The authors report that the sample included institutions of different types and regions. Generalizability within Saudi Arabia remains uncertain because institution selection and project sampling are not adequately described. By using objective records and multiple compliance indicators, we obtained a nuanced picture [38]. One limitation is reliance on documented records; it's possible that some compliance lapses were not recorded, meaning true non-compliance could be higher [39]. We also did not directly survey investigators, which could provide insight into reasons for non-compliance (e.g., lack of awareness or training) [40]. Additionally, our data spanned a decade during which awareness of the law might have increased over time – we observed improvements in recent years, suggesting a trend that we did not analyze longitudinally in depth. Future studies could evaluate compliance trends over time or assess the impact of specific interventions, like training programs, on improving research ethics adherence.

Conclusions

The audit describes documentation in projects at participating institutions. A missing record leaves approval or consent status unresolved. Comparisons require consistent project-level definitions and inference that accounts for clustering within institutions.

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