

Introduction to Health Informatics Ethics and Legal Issues

Introduction to Health Informatics – Ethics & Legal Issues
Designed as a quick-reference guide for students and professionals

1. Core Concepts

Term	Definition	Why It Matters
Health Informatics	Application of information technology to collect, store, retrieve, and use health data.	Enables evidence-based care, research, and public health monitoring.
Ethics	Moral principles that guide professional behavior (e.g., beneficence, autonomy).	Protects patient dignity and trust.
Legal Issues	Statutes, regulations, and case law that govern how health data can be handled.	Provides enforceable standards and liability protection.

2. Ethical Principles in Health Informatics

Principle	Practical Implications	Example
Beneficence	Systems must improve health outcomes.	Clinical decision support that reduces medication errors.
Non-maleficence	Avoid causing harm through technology.	Rigorous testing of AI algorithms before deployment.
Autonomy	Respect patients' right to control their data.	Providing clear consent options for data sharing.
Justice	Fair distribution of benefits and burdens.	Ensuring underserved populations have equal access to telehealth.
Privacy & Confidentiality	Safeguard personal health information (PHI).	Encryption of data at rest and in transit.
Transparency	Make data processes understandable.	Publishing model performance metrics for an AI diagnostic tool.
Accountability	Assign responsibility for data handling.	Audit trails that identify who accessed a record and when.

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3. Key Legal Frameworks (U.S. focus – note variations worldwide)

Legal Issues

Law / Regulation	Scope	Major Requirements
HIPAA (1996)	All “covered entities” & business associates handling PHI.	• Minimum Necessary use • Safeguards (administrative, physical, technical) • Breach Notification (within 60 days)
HITECH Act (2009)	Extends HIPAA to include breach?notification incentives & penalties.	• Mandatory breach reporting to HHS & affected individuals • Increased fines for non?compliance
21st Century Cures Act (2016)	Promotes data interoperability & patient access.	• Prohibits information blocking • Requires APIs for EHR data sharing
GDPR (EU, 2018)	Applies to any organization processing data of EU residents.	• Lawful basis for processing • Data subject rights (access, erasure, portability) • Data Protection Impact Assessments (DPIA)
State?level laws (e.g., California Consumer Privacy Act – CCPA)	Adds consumer?focused privacy rights.	• Opt?out of data sale • Right to know what data is collected
FDA Regulations (for software as a medical device – SaMD)	Governs clinical decision?support tools, AI/ML algorithms.	• Pre?market clearance/approval • Post?market surveillance and reporting

4. Common Ethical & Legal Challenges

Challenge	Ethical Tension	Legal Implication	Mitigation Strategies
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Data Sharing

Across Borders

AI/ML Bias

Autonomy vs.
public?health
benefit

Justice & non?
maleficence

Legal Issues

Conflict between GDPR
and local privacy laws

Potential liability for
discriminatory outcomes

Use data?localization

agreements; anonymize/de?

identify before export

Conduct