

HCI Code of Ethics and Conduct

1. Introduction

HealthCare Innovation (HCI) operates at the confluence of **clinical innovation, public interest, and entrepreneurial development**. This requires a governance model built on **ethics, transparency, scientific integrity, impartiality, and respect for human dignity**.

This extended Code of Ethics document outlines the **principles, safeguards, processes, responsibilities, and operational mechanisms** that ensure ethical conduct across the entire health innovation lifecycle supported by HCI.

It complements the shorter version published on the website and is meant to guide:

- Board and staff members
- Experts, evaluators, and mentors
- Startup founders and innovation teams
- Contractors and partners
- Academic and clinical collaborators
- Participants in HCI programs and Living Labs

2. Ethical Principles & Foundational References

HCI's ethical governance is inspired by internationally recognized frameworks, including:

- **Bogotá Principles on Ethical Business Practices in the Medical Device Sector**
- **Tunisian Code of Medical Deontology**

- WHO guidelines on digital health and data ethics
- EU MDR (2017/745) and AI Act – principles on safety, transparency, and human oversight
- OECD Principles on Good Laboratory & Scientific Practice
- UN and World Bank Integrity Standards

These frameworks shape HCI's commitment to **responsible innovation**, especially in contexts involving:

- Health data
- Vulnerable populations
- Emerging technologies
- Market access and regulatory pathways
- AI-enabled healthcare solutions

3. Ethical Responsibilities of HCI Members & Representatives

3.1 Duty of Honesty & Transparency

All representatives must:

- Communicate accurately about responsibilities, roles, and outcomes
- Avoid misleading, exaggerated, or unverified claims
- Disclose affiliations and potential biases

3.2 Duty of Professionalism

Members must maintain:

- Professional conduct at events, workshops, and evaluations
- Respectful interactions with patients, clinicians, students, and innovators
- Cultural sensitivity and inclusive communication

3.3 Duty of Confidentiality

All non-public information shared during programs, mentoring, regulatory discussions, or co-creation sessions must remain confidential unless explicit written authorization is provided.

4. Conflict of Interest (COI) Governance Framework

To preserve impartiality and avoid undue influence in competitive or evaluative settings (funding calls, startup selections, procurement, program admissions):

4.1 Annual Declaration of Interests

All board members, technical experts, and evaluators must submit:

- A declaration of commercial, academic, or familial interests
- Updates whenever circumstances evolve

4.2 COI Screening

HCI conducts routine COI checks before:

- Evaluation panels
- Startup mentoring assignments
- Procurement decisions
- Grant and funding competitions
- Regulatory or market-access advisory sessions

4.3 Recusal Protocol

Individuals must:

- Declare a conflict immediately
- Withdraw from assessment, discussion, or voting
- Allow the committee to document the recusal

Non-compliance is considered **ethical misconduct**.

5. Scientific & Research Integrity Framework

Scientific integrity is non-negotiable. HCI adheres to the following principles:

5.1 Research & Clinical Ethics

All projects under HCI must:

- Respect patient privacy and dignity
- Secure necessary approvals for clinical or observational studies
- Avoid overstating scientific evidence
- Maintain transparent methods and traceable records

5.2 Unacceptable Practices

The following constitute **zero-tolerance violations**:

- Falsifying clinical data or performance metrics
- Manipulating outcomes to obtain funding

- Claiming regulatory approval when none exists
- AI model “hallucination” passed as validated data
- Plagiarism of papers, algorithms, regulatory dossiers, or technical documentation

5.3 Startup Sanctions

Startups violating scientific integrity standards may face:

- Suspension from programs
- Revocation of cluster membership
- Public correction or withdrawal of misleading claims
- Referral to regulators or academic institutions

6. Ethical Collaboration with Hospitals, Universities & Physicians

HCI's collaborations follow strict ethical boundaries:

6.1 No Undue Influence

Relationships with healthcare providers must avoid:

- Gifts, compensation, or incentives that could influence decisions
- Preferential treatment for specific vendors or startups
- Hidden financial interests in evaluations or pilot studies

6.2 Transparency in Co-Creation

Co-creation activities must:

- Clearly define responsibilities and data ownership
- Respect deontological and professional conduct rules
- Prevent misuse of clinical authority

7. Marketing & Communication Ethics

7.1 Truthful Representation

All communication — internal or external — must:

- Be evidence-based
- Avoid sensationalizing innovation
- Clearly distinguish between prototypes, pilots, and validated technologies

7.2 AI & Digital Health Claims

AI/ML-based solutions must not:

- Present unvalidated accuracy rates
- Imply diagnostic capabilities without regulatory authorization
- Suggest medical benefits unsupported by clinical studies

8. Data Ethics & Protection Principles

Regardless of project location, HCI applies:

- **Tunisian Data Protection Law (2004-63)**
- **GDPR principles** when working with EU partners
- Ethical data usage aligned with WHO Digital Health Ethics

8.1 Core Data Ethics Values

- Purpose limitation
- Minimal collection
- Transparency with users and patients
- Secure storage and role-based access
- Clear governance of shared data in pilots and Living Labs

8.2 High-Risk Data Handling

Any activity involving:

- Health data
- Biometric data
- AI model training datasets
 - must follow strict DPIA-style assessments and ethical review.

9. Anti-Corruption & Integrity Measures

To maintain trust and credibility:

9.1 Prohibited Practices

- Kickbacks
- Favoritism in startup selection
- Insider information misuse
- Hidden financial relationships
- Improper influence on hospital or ministry partners

9.2 Procurement Ethics

All procurement follows:

- Transparent criteria
- Competitive processes
- Documented decisions
- COI checks for involved staff

10. Implementation Mechanisms

This Code of Ethics is operationalized through:

- Mandatory ethics onboarding for all staff and startups
- Annual training for evaluators and mentors
- Documentation of COI and recusals
- Safeguarding integration (PSEAH policy)
- Startup compliance reviews during programs
- Monitoring of scientific integrity risks
- Disciplinary procedures for violations

11. Reporting Ethical Concerns

Individuals are encouraged to report misconduct, violations, or unethical behavior.

All reports are:

- Treated confidentially
- Protected under anti-retaliation guidelines

- Investigated fairly and objectively

Anonymous submissions are accepted.

12. Enforcement & Disciplinary Actions

Depending on severity, sanctions may include:

- Verbal or written warnings
- Mandatory corrective training
- Removal from committees or roles
- Suspension from projects
- Termination of collaboration
- Revocation of HCI membership
- Notification to professional bodies or regulators

13. Document Review & Governance

This extended Code of Ethics document is reviewed:

- **Annually**, or
- When significant regulatory or sector changes occur

The Ethics Committee recommends updates to the Executive Board.