

# 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.