CMPUT 605

**Ethics in the Software Development Life Cycle:
A Case Study of Health Informatics Systems**

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Review of Last Meeting

- Review of FDA document
- Discussion about **Introduction** section of final report
- Next meeting
  - Looking into levels of risk in FDA document
  - Looking at Canada, USA, Europe
  - Review of IMIA/BCS code of ethics
  - **Introduction** section of final report

Code of Ethics for Health Informatics Professionals

- British Computer Society [BCS] published 2003
- International Medical Informatics Association [IMIA] published in October 2002
- United Kingdom Council for Health Informatics Professions (UKCHIP)
- One of the authors
    - Dr. Eike-Henner W. Kluge, Professor, Department of Philosophy, University of Victoria, BC, Canada

Canada

- COACH: Canada's Health Informatics Association
- COACH code of ethics (for COACH members)
    - Abridged version available free published 2006
- Guidelines for the Protection of Health Information (focuses on privacy and security)
    - Summary version available free published 2009

USA

- FDA draft published June 1997
- FDA document current version published January 2002
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
    - Defines "Level of Concern"

USA

- American Health Information Management Association (AHIMA) Code of Ethics published July 2004
- A Code of Professional Ethical Conduct for the American Medical Informatics Association [AMIA] published August 2007 (references IMIA and AHIMA codes)

World

- World Health Organization Eastern Mediterranean Regional Office [WHO EMRO] eHealth code of ethics published May 2000

Chronology

FDA Version 1.1	1997
WHO eHealth COE	2000
FDA Version 2.0	2002 Jan
IMIA COE for HIPs	2002 Oct
BCS HI COE	2003
AHIMA COE	2004
COACH COE	2006
AIMA COE	2007

BCS HI Code of Ethics

- Fundamental ethical principles
- Principles of informatic ethics
- Ethics for health informatics professionals

Fundamental Ethics

- All social interactions subject to these
    - Autonomy
    - Equality and justice
    - Beneficence
    - Non-malfeasance
    - Impossibility
    - Integrity

Informatic Ethics

- Fundamental principles applied to situations that characterize the informatic setting
  - Privacy
  - Openness
  - Security
  - Access
  - Legitimate infringement
  - Least intrusive alternative
  - Accountability

Health Informatics Ethics

- Informatic ethics applied to professional relationships and circumstances of health informatics professionals
    - Subject-centered duties
    - Duties towards health care professionals
    - Duties towards institutions/employers
    - Duties towards society
    - Self-regarding duties
    - Duties towards the profession

Subject-centered

- Duties to subjects/patients the HI professional interacts with
- Consent/awareness of subject about storage of electronic records about them
- HI professional safeguards security, integrity, usability, accessibility

Health Care Professionals

- Medical personnel who use HI systems
- Ensuring usability, technical quality, assistance

Institutions/Employers

- Competence
- Diligence
- Integrity
- Loyalty

Society

- Educating the public about issues related to storage, collection, nature and use of electronic data
- Uphold human rights

Self-Regarding

- Recognizing and acknowledging limits of their competence
- Consult with others
- Maintain competence by re-training
- Avoid conflict of interest
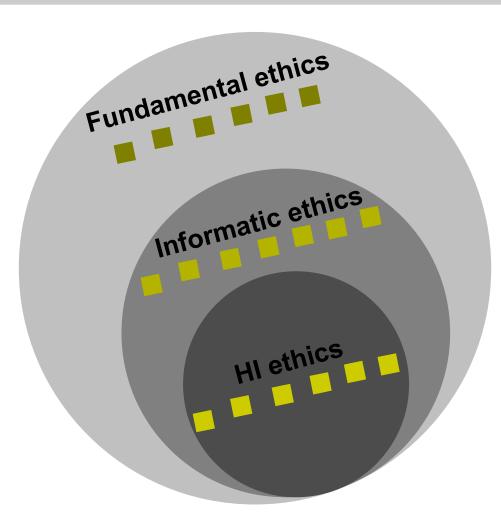- Give appropriate credit for work done
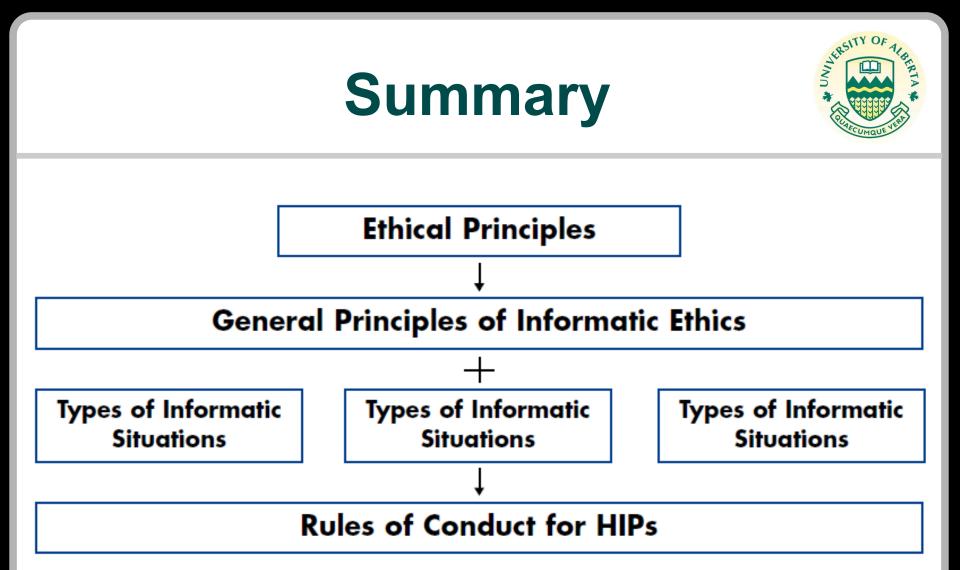- Take responsibility

Profession

- Not to bring the profession into disrepute
- Not impugning the reputation of colleagues
- Assisting colleagues in living up to technical standards

Summary

Summary

Image from BCS document

Plan for Reading Week

- ## Reading
  - ### WHO eHealth COE
  - ### FDA guide containing levels of risk
  - ### AMIA COE
  - ### AHIMA COE
  - ### Book
- ## Writing
  - ### Review **Introduction** section
  - ### Next section on **Background**