“Doing the right thing”

• “Real integrity is doing the right thing, knowing that nobody’s going to know whether you did it or not.”
  Oprah Winfrey

• Above any existing law or regulation, it is our duty to conduct research in a manner consistent with proper and responsible conduct of individuals expected in the University community.
Protection from Risks

• Typical examples of harm in social and behavioral science research:
  • Emotional or psychological harm
  • Social harm
  • Physical harm
  • Financial harm
  • Legal harm
  • Moral harm

• It is our duty to minimize these potential risks
What is research? Who are subjects?

• The law defines research as the systematic investigation that contributes to generalizable knowledge.

• An investigator is engaged in research if s/he has proposed an intention to explore a particular topic, while interactive with one or more living persons (the subjects), and either publish the results in a journal or present at a conference.

• The subjects are the living individuals about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.
What is an IRB?

An institutional review board (IRB), also known as an independent ethics committee (IEC), ethical review board (ERB) or research ethics board (REB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

http://irb.ucsd.edu
Ethics – it’s the law

• 45 CFR 46 – Protection of Human Subjects
  • Ensures minimal standards for the treatment of human research subjects.
  • Based on the recommendations of The Belmont Report, released April 18, 1979 after the discovery of the Tuskegee experiments.

• Foundations of ethics in human research
  • Freedom from harm
  • Privacy
  • Voluntary participation
Historical Perspective

Human Research Abuses

• 1940’s
  • Nazi war crimes

• 1950’s
  • Thalidomide Tragedy

• 1960’s
  • Human Radiation Experiments
  • New York City’s Jewish Chronic Disease Hospital
  • Willowbrook Studies
  • Milgram Study

• 1970’s
  • Tuskegee Syphilis
  • Stanford Prison Experiment
Historical Perspective
Response to Research Abuse

- Nuremberg Code (1948)
- Declaration of Helsinki (1964-2013)
  - Call for Journal editors to require ethical review
  - Call for national policy on IRB review
- The National Research Act (1974)
- Set-up formal IRBs
- Belmont Report (1979)
- 1990s – tightening of the regs because of continued abuse
- 2007 – loosening of some interpretations when applied to social, behavioral and educational research
Nuremberg Code (1947)

- Established after the Nuremberg Trial (Germany, 1946) resulting in the conviction of 16 of the 23 Nazi physicians (7 sentenced to death).

- Voluntary consent
- Anticipate scientific benefits
- Benefits outweigh risks
- Animal experiments first
- Avoid suffering
- No intentional death or disability
- Protection from harm
- Subject free to stop
- Qualified investigators
- Investigator will stop if harm occurs
Declaration of Helsinki (1964 — 2013)

- The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

- The first version was adopted in 1964 and has been amended seven times since, most recently at the General Assembly in October 2013 in Fortaleza, Brazil. The current (2013) version is the only official one.

• In 1974, the National Research Act was enacted by US Congress.

• It created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to oversee and regulate the use of human experimentation in medicine.

• This Act was developed as partly a response to the disastrous Tuskegee Syphilis Study.

• The National Research Act mandated specific requirements for institutional review committees which became known as Institutional Review Boards (IRBs).

• The Belmont Report Guided IRBs establishment
The Belmont Report

- Established Responsibilities

- IRB must ensure that the researcher and the participant distinguish clinical practice from research.

- IRB must minimize the potential for therapeutic misconception.

- Ethical Principles

- Respect, Beneficence, Justice
Categories of Risk

- **Minimal risk**: The risks of harm are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- **More than minimal risk**: Risks exceed, either in probability or magnitude, those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
Risks in Behavioral and Social Research

• Invasion of privacy
• Breach of confidentiality
• Embarrassment
• Stigma
• Psychological Trauma
Belmont Report: Respect

• Individuals should be treated as autonomous agents

• Persons with diminished autonomy are entitled to protection (‘special populations’)
  • Children
  • Mental disabilities
  • Prisoners
Belmont Report: The Common Rule

- “An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.”

- 45 CFR 46.116
Belmont Report: Beneficence

- Do no harm

- Maximize possible benefits and minimize risks

- Applied at both an individual level for research participants and a societal level for the effect of the knowledge gained from the research
Belmont Report:
Justice

• fair distribution of the burdens and benefits of research

• selection of research participants should involve those groups who will benefit from research, not ‘convenience’ populations that are more likely to be disadvantaged
Informed Consent

• Purpose

• Procedures

• Voluntary Participation

• How the information will be used

• How to opt out at any point

• How to contact the researcher

• Signatures
Informed Consent

• May be coercive if
  
  • Subjects are in a group when recruited and there is an unspoken expectation that they should participate because of their membership in the group, e.g. students, racial affiliation
  
  • Compared to the study subjects, the investigator has a position of socio-economic status and/or expertise, e.g. doctor or professor
  
  • The technical jargon makes subjects feel intimidated and/or prevents understanding
Exemptions

• Research on educational practices or for educational purposes

• Educational tests and surveys of subjects cannot be identified

• Educational tests and surveys of public officials

• Research on existing data if it is public or deidentified

• Quality assurance and evaluation

• Taste and food quality evaluation and consumer acceptance studies (these are covered by the FDA)
Summary: When is research taking place with human subjects?

• Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The knowledge is published or presented in a public forum.

• Human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction, or 2) identifiable private information.
Remember!

- Independently if your project is considered or not research with human subjects, you still have to follow ethical and legal principles.

- *Real integrity is doing the right thing, knowing that nobody’s going to know whether you did it or not.*

  Oprah Winfrey
More Resources

• http://irb.ucsd.edu
• http://www.citiprogram.org
• http://www.hhs.gov/ohrp
• http://www.fda.gov
• http://www.hhs.gov/ocr/privacy/
Health Insurance Portability and Accountability Act

HCI4H - Winter 2018
Nadir Weibel, PhD
WHAT IS HIPAA?

Health Insurance Portability and Accountability Act of 1996

A Federal law imposed on all health care organizations including hospitals, physician offices, home health agencies, nursing homes and other providers, as well as health plans and clearinghouses, that protects patient health information.
HIPAA

- Health Insurance Portability and Accountability Act
- Privacy Rule
- Initially effective April 14, 2001
- Modified August 14, 2002
- Final Implementation April 14, 2003
- HITECH March 2010
Purposes of HIPAA Compliance

- To protect and enhance the rights of consumers by providing them access to their personal identifiable health info and controlling the inappropriate use of that info.

- To improve the efficiency and effectiveness of health care delivery by creating a national framework for health privacy protection that builds on efforts by states, health systems, and individual organizations and individuals.
Patients

• Gives more control to the patients over their health information:
  - Gives patients the right to examine and obtain a copy of their health records and request corrections.
  - How the info may be used.
  - Limits the amount of info released.
Healthcare Providers

- Sets boundaries on the use and release of health records
- Establish safeguards to protect the privacy of health info
- Holds violators accountable
PHI and PII

- **PHI = Protected Health Information**
  - Medical record number, account number or SSN
  - Patient demographic data, e.g., address, date of birth, date of death, sex, e-mail / web address
  - Dates of service, e.g., date of admission, discharge
  - Medical records, reports, test results, appointment dates

- **PII = Personally Identified Information**
  - Individual’s name + SSN number + Driver’s License # and financial credit card account numbers
Protected Health Information

- Health information
- Pertaining to an individual’s past, present, or future:
  - Physical or mental health
  - Diagnosis and/or treatment
  - Payment for health care
- That includes personal identifiers, and
- That is created, used, or disclosed by a Covered Entity.
Personal identifiers under HIPAA are:

- Name
- Address including city and zip code
- Telephone number
- Fax number
- E-mail address
- Social security number
- Account number
- Certificate/license number
- Device identifiers and serial number
- Vehicle identifiers and serial number
- URL
- IP address
- Biometric identifiers including finger prints
- Full face photo and other comparable image
- Date of birth
- Medical record number
- Health plan ID number
- Dates of treatment
Patient Rights

- To know how their PHI will be used and disclosed
- To request additional protection
- To request a copy of their medical records
- To request an amendment to their medical records
- To have an accounting of disclosures of PHI
- To refuse to sign the acknowledgement

Patient does not need to sign in order to be treated.
Research

- Individual authorization
- Institutional Review Board (IRB)

See Assignment 1

http://irb.ucsd.edu
Confidential Information

HIPAA DON'T'S

• Don’t tell anyone what you may overhear regarding a patient.

• Don’t discuss a patient in public areas such as elevators, hallways, or cafeterias.

• Don’t look at information about a patient unless you need to as part of your job.

• Don’t look up information about friends or relatives unless you need to to perform your work.
Confidential Information
HIPAA DO’S

• Do keep all information you hear about a patient to yourself.

• Do dispose of patient information by placing in properly designated shredder bins for destruction.

• Do notify security if you see an unescorted visitor in a non-public area of the hospital.
Questions that are frequently asked in regard to HIPAA
Frequently asked Questions

• Can medical practitioners access patient’s medical info in the course of their training?

  Yes. Health care operations definition provides for learning under supervision. Minimum necessary.
Frequently asked Questions

• Does a provider need a patient’s written authorization to send a copy of his/her medical record to another health care provider who will treat the patient?

• No, Minimum necessary does not apply.
Frequently asked Questions

• Are appointment reminders allowed without authorization?
  
  • Yes, unless agree to additional protections requested by the patient.
Frequently asked Questions

• Can a physician’s office FAX patient medical info to another physician office?

• Yes. For treatment purposes with reasonable safe guards i.e. confirming the current fax number and the fax machine is in a secure location.
Let’s Play: Privacy and Security Training Games

http://www.healthit.gov/sites/default/files/cybersecure/cybersecure.html

Human Computer Interaction for Health
Week 2 - Essays and Site Visits

HCI4H - Winter 2018
Nadir Weibel, PhD
Essays

• Reflect on the consequences and opportunities for interactive technology in the specific settings
  • Role of Technology
  • Role of People

• Include references to related research, methodology, theory or technology.

• Specific perspective (researcher, end-user/patient, clinician, Boethical Research, entrepreneur).
  • Be sure to make that topic clear to your readers.
Essays

• Deadlines
  • Friday 12pm (noon): initial version
  • Tuesday 2pm: final version

• Peer Reviews
  • As many as you want, but at least 3 reviews for the draft and for the final
  • Start reviewing and getting feedback after 12pm on Friday
  • Reviews on initial version by Sunday night
  • Reviews on final version by Thursday night

• Grading
  • 40% of the overall grade (25% essay, 15% reviews)
Essay Rubric

Style

• **Poor**: The essay is not objective and addresses poorly the issues referred in the proposed topic. The provided information is not necessary or not sufficient to discuss these issues.

• **Good**: The essay is objective and for the most part addresses with an in depth analysis most of the issues referred in the proposed topic. The provided information is, for the most part, necessary and sufficient to discuss these issues.

• **Excellent**: The essay is objective and addresses with an in depth analysis all the issues referred in the proposed topic. The provided information is necessary and sufficient to discuss these issues.
Essay Rubric

Quality of Writing

- **Poor**: The essay is not well written, and contains many spelling errors, and/or grammar errors and/or use of English errors. The essay is badly organized, lacks clarity and/or does not present ideas in a coherent way.

- **Good**: The essay is well written for the most part, without spelling, grammar or use of English errors. The essay is for the most part well organized, clear and presents ideas in a coherent way.

- **Excellent**: The essay is well written from start to finish, without spelling, grammar or use of English errors. The essay is well organized, clear and presents ideas in a coherent way.
Perspectives

• For each visit your group will be assigned a different perspective
  • Researchers
  • Clinicians / Healthcare Professionals
  • Patients/Users
  • Bioethicist / Human Research Protection (IRB)
  • Entrepreneur

• Your essay should focus on your view of HCI4H in the setting of the site visit from this particular perspective
Essay Rubric

Visit Specifics

• Was the overall visit discussed?
• Was the role of people in this setting discussed?
• Was the role of technology in this setting discussed?
• Was the essay's unique perspective presented?
Essay Rubric: Reading Class and Material

- Links to the weekly class readings
- References to class material and activities
Next...

- THURSDAY: Site Visit
- Center for the Future of Surgery (CFS)
Site-Visit

• The Center for the Future of Surgery, situated in the newly opened Medical Education and Telemedicine (MET) Building in La Jolla, offers medical simulation training. It is dedicated to educating surgeons and testing new operating room equipment, procedures and techniques.

• 2PM: CFS, MET Building

• Meet outside of the MET Building, by the stairs that descends into the CFS
MET and SCT

https://maps.ucsd.edu/map/?id=1005&mrkId=163876
Readings for Week 1


2. Fieldwork for Healthcare - Case studies: Ch 5, "Finding Balance: Matters of Ethics, Consent, and Emotional Work When Studying Handover in Hospitals"

3. Fieldwork for Healthcare - Guidance: Ch 1, "Ethics, Governance, and Patient and Public Involvement in Healthcare"
Readings for next Week

1. Fieldwork for Healthcare - Case studies: Ch 4, "Observing Healthcare: An Exploration of Observer Experiences and Emotion"

2. Fieldwork for Healthcare - Case studies: Ch 6, "Fieldwork and Challenges of Access"

3. Fieldwork for Healthcare - Guidance, Ch 2: "Readying the Researcher for Fieldwork in Healthcare"

Assignment 1
CITI/HIPAA Training

https://www.citiprogram.org/

irb.ucsd.edu/hipaatutorial/login.shtml

Start in Class on today
due Thursday 1/18 2pm, before class.