Human Subjects in Research

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National Research Act

- Signed into law 1974
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- Belmont Report
Protection of Human Subjects
Belmont Report

- *Respect for persons* = informed consent
- *Beneficence* = risk/benefit analysis
- *Justice* = appropriate selection of subjects
Regulations

- Common Rule (19 agencies)
  - 45 CFR 46 A, B, C, and D
- FDA (Investigational Products)
  - 21 CFR 50 and 56
- HIPAA (Protected Health Information)
  - 45 CFR 160, 162, 164

http://www.udel.edu/research
Additional Regulations

Funding Source

- Department of Defense (32 CFR Part 219)
- Department of Education (34 CFR Part 97)
- Department of Justice (28 CFR Part 46)
- Department of Veterans Affairs (38 CFR Part 16)

Investigators should review the regulations of the funding agency to determine whether additional regulations apply
International Research Regulations

• Declaration of Helsinki (1964-2008)
  – World Medical Association

• CIOMS (1993, 2002)
  – World Health Organization, UNESCO

(http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html)
The Federalwide Assurance

- FWA00004379 University of Delaware
  - Compliance with U.S. Department of Health and Human Services (DHHS)
  - Applies to ALL human subjects research

- IRB00000472
Human Subjects Procedures

• **Training** for the protection of human subjects in research is required for all researchers (faculty, students, staff) who will be directly interacting with research participants or who will have access to identifiable private information.

UD Protocol and Approval Procedure

• All research involving human subjects must be reviewed and approved by the UD IRB which meets monthly.
  – Submit protocol through [http://www.irbnet.org](http://www.irbnet.org)
  – See Research Calendar for submission deadlines and meeting dates [http://www.udel.edu/research/researchers/calendar.html](http://www.udel.edu/research/researchers/calendar.html)
Institutional Review Board (IRB)

- Approves, monitors, and reviews all research involving human subjects
- Members include scientists, non-scientists, prisoner-advocate, and community representatives
- Review at convened meetings with a majority of members present (quorum)
IRB Responsibilities

• Initial Review and approval of protocols
• Continuing review of existing protocols
• Suspend or terminate previously approved research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to subjects
Determination of Risk

Minimal risk means probability of harm or discomfort is no greater than that encountered in daily life or during the performance of routine physical or psychological examinations or tests
Levels of Review

- **Exempt** (Minimal Risk; 6 Categories)
  - Granted by the Chair or IRB designee
  - Approval for 3 years

- **Expedited** (Minimal Risk; 9 Categories)
  - Reviewed on a rolling basis by one or more IRB members
  - Requires annual continuing review

- **Full Board Review**
  - Reviewed by convened IRB at monthly meeting (see research calendar)
  - Requires at least annual continuing review

http://www.udel.edu/research/preparing/humansub-protocolreview.html
Recordkeeping Requirements

• All materials related to project must be retained for 3 years after project completion
  – Consent forms
  – Protocol documents

Guidance on Data Storage and Retention
http://www.udel.edu/research/preparing/datastorage.html
Investigator Responsibilities

- Comply with appropriate regulations
- Obtain prior IRB approval
- Implement research as approved
- Obtain and document informed consent/assent
- Obtain prior approval for deviations from protocol (amendment)
- Submit continuing review reports as required by IRB
- Promptly report unanticipated problems and adverse events
- Appropriate record keeping

http://www.udel.edu/research
ANPRM
Major Proposed Changes to the Common Rule

• Ensuring Risk-Based Protections
• Streamlining IRB Review of Multi-Site Studies
• Improving Informed Consent
• Strengthening Data Protections to Minimize Information Risks

http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html
University of Delaware Policy and Procedures

- UD research policy 6-4
  http://www.udel.edu/ExecVP/polprod/6-04.html
- UD human subject protocol submission procedures
  http://www.udel.edu/research/preparing/protocolreview.html
- IRB Standard Operating Procedures
  http://www.udel.edu/research/preparing/irb-sop.html