REHAB 427
Applied P&O 1
Spring 2009

Course Revision

- Presentations cancelled
- Student-lead discussions (8:30 – 10:30am)
  - May 13th – Jen, Cedar, Random, Paula
  - May 20th – Kim, Megan, Jean, Greg
  - May 27th –Adrienne, Brandon, Matt
  - June 3rd – No class
- 30 minutes per student
- "Open" format
  - All students assessed based upon evaluation criteria
- Papers due on 3/10/2009 by 5pm
  - Paper and electronic (email)

The Research Proposal

REHAB427 research proposal

Section	# of Pages
• Title	0
• Abstract	1
• Description of the problem	1-2
• Literature review	3-6
• Proposed research	1-2
– Purpose	
– Question/hypothesis	
– Specific Aims	
• Methodology	2-5
• Subject protection	1-2
• Resources	1-2
TOTAL	**10-20**

Ethics, Personnel & Budget

Ethics

Ethical Responsibility

- Three principles of ethical research*
  - Autonomy – right of self-determination
    - Individuals make their own choices
    - Researchers must respect that choice
      - Especially important with children, disabled persons
  - Beneficence – responsibility of well-being
    - "Do no harm" or max. benefit while min. *possible* harm
    - Researcher must weight benefits with risks
  - Justice – fairness in the research process
    - Equality of benefits and burdens (i.e. controls)
    - Proper selection of research candidates
    - Applicability of question and research

* Portney & Watkins ©2000

History

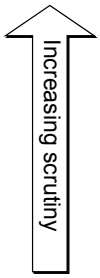
- Rights and protection for human subjects
  - Derived from issues of human experimentation
    - Cancer study (1960's)
    - Syphilis study (1930's – 1970's)
- *Nuremburg Code* (1947)
  - First formal document
  - Research only by a qualified professional
  - Subjects must give <u>*informed consent*</u>
    - Purpose, procedures, inconveniences, and potential hazards
- *Declaration of Helsinki* (1964, 1975, 1983, and 1989)
  - World Medical Association
  - First to address <u>independent review</u>
  - Invalid research should not be accepted for publication
  - Incorporated by US Dept of Health and Human Services (DHHS) Rules & Regulations

Independent Review

- US laws state all federally-funded research must be reviewed
- Most institutions require internal review for *all* research
- Internal Review Board (IRB)
  - At least 5 members
  - Mix of males and females
  - Not from same professional group
  - Competent for review
  - One member must be nonscientific
    - Lawyer, clergy, ethicist
  - One must be unaffiliated with institution
- IRB Review
  - Consider scientific merit
  - Evaluate competency of researchers
  - Assess risk to subjects ("risk-to-benefit")
  - Interpret feasibility of study given available resources
  - Results in approval, require modifications, or disapproval

Types of Review

- Full review
  - 5 reviewers
  - Longer review process (many months)
- Expedited review
  - 2 reviewers
  - Less time for approval (weeks to months)
  - Specific study characteristics
    - Non-invasive procedures w/ adults
    - Routinely applied interventions
    - Moderate exercise w/ healthy subjects
- Exempt review
  - At least one reviewer
  - Study characteristics
    - Surveys
    - Interviews
    - Review of records
  - Non-identifying information
  - Non-personal information (no drug, criminal, or sexual activity)



Informed Consent

- Informational elements
  - Subjects must be fully informed
    - Purpose of research
    - Explanation of procedures
    - Risks (i.e. physical, psychological, emotional, financial, etc.)
    - Benefits (i.e. no direct benefit, reduced pain, payment, etc.)
  - Subjects information should be protected
    - Confidential
    - Anonymous
  - Transfer of information must be clear
    - Lay language
    - Written and/or verbal
  - Subjects must be free to question researchers
    - Time to assimilate

Informed Consent

- Consensual elements
  - Voluntary consent
    - No penalty for not participating
    - No penalty for not completing (including compensation)
  - Vulnerable subjects
    - Children
    - Disabled persons
    - Require parent/guardian consent
  - Withdrawal
    - Voluntary withdraw at any time, for any reason
      - Before
      - During
      - After
    - Withdrawal for safety concerns

Does this complicate research?

Informed Consent

- Consent form
  - Typed
  - Incorporates all elements of informed consent
  - Signed and dated
    - Subject
    - Researcher (and witness)
    - Signature page must contain text of consent form
  - Copies
    - Subject and researcher's files
    - Kept separate from study data
- Exclusions to informed consent
  - Retrospective review of non-identifying patient data
  - IRB is still required

Patient Information

- Health Insurance Portability and Accountability Act (HIPAA)
  - Developed to transfer patient information (1996)
- HIPAA Privacy Rule
  - Set of privacy regulations incorporated into HIPAA (2004)
  - Most organizations must be HIPAA-compliant
- Protected health information (PHI)
  - Past, present, future physical or mental conditions
  - Treatment options for those conditions
  - Payment information regarding treatment
  - May be electronic, written, or verbal
  - Patient may be living or a decedent
- Different types of PHI
  - Individually identifiable health information (IIHI)
  - De-Identified information
  - Limited dataset

HIPAA

http://www.hhs.gov/ocr/hipaa/

Health Information

- Rules of access and use
  - Differ for each type of PHI
- Individually identifiable health information (IIHI)
  - IIHI is created or received by a healthcare provider
  - Involves medical (physical or psychological) conditions
    - Past, present or future
  - Involves treatment of medical conditions
  - Involves payment information regarding medical conditions
  - Identifies the individual

Access and use of IIHI requires consent from patient

De-identified information

1. Name
2. Location more specific than state
3. Dates (birth, admission, discharge, death, age over 89)
4. Telephone number
5. Fax number
6. Email address
7. Social security number
8. Medical record number
9. Health plan number
10. Account number
11. Certificate/license numbers
12. Vehicle identifiers and numbers (VIN, license plate, etc)
13. Device identifiers and serial numbers
14. Website information (URL)
15. Biometric identifiers (voice or finger prints)
16. Identifying photographs (face, tattoos, etc)
17. Internet address (IP address)
18. Any other unique identifying information

Access and use of de-identified information **MAY NOT** require consent from patient

Limited Dataset

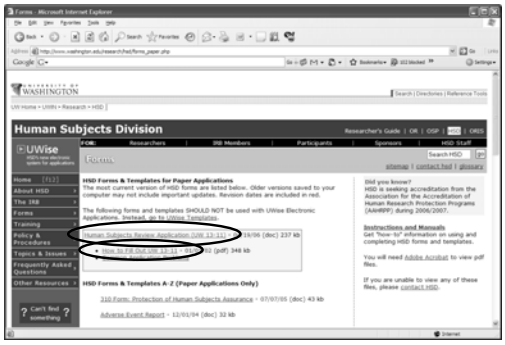
- Must be removed
  - Name
  - Address (other than city, state, and zip)
  - Telephone and fax number
  - Email address
  - Social security number
  - Certificate/license information
  - Vehicle identifiers and numbers
  - URL's and IP addresses
  - Identifying photographs
  - Medical record, health plan, or account numbers
  - Device identifiers and serial numbers
  - Biometric identifiers
- Are allowed
  - Admission, discharge, service dates
  - Birth and death dates
  - Age
  - Geographical information (city, state, zip, etc.)

Access and use of limited datasets requires data use agreement with institution

HIPAA Authorization

- Analogous to informed consent
  - What information will be used
  - Who will have access to the information
  - Who may receive the information
  - Purpose of collecting/disclosing the information
  - Expiration of information
    - Often 5 years
    - If indefinite, explicitly state so
  - Patient signature and date
  - Right to revoke information
  - Right to non-participation

UW Human Subjects Form



Human Subjects Review

- Key review items
  - Researcher contact information
  - Approval from chair/dean/director
  - Co-investigators
  - Funding sources
  - Purpose
  - Procedures/protocol
  - Deception
  - Number, age, gender, ethnicity of subjects
  - Inclusion/exclusion criteria
  - Recruitment procedures
  - Risks and benefits
  - Adverse effects
  - Confidentiality
  - Informed consent

Residency Research

- Question: given these rules, how do I get started?
- Answer: HIPAA allows limited access to PHI

- Preparatory research
  - Formulate a research proposal
  - Creating a hypothesis
  - Identifying candidate subjects
- Subject recruitment
  - As an employee you can
    - Identify subjects
    - Contact subjects for authorization
  - Cannot extract PHI from patient files w/o authorization

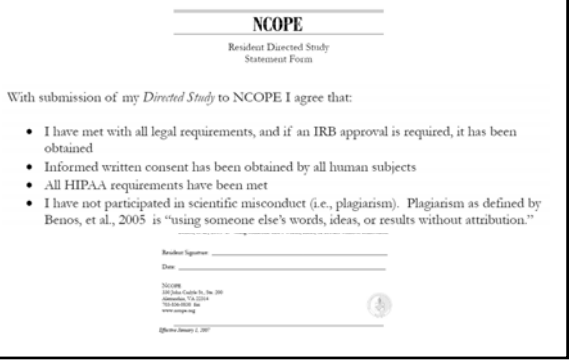
http://privacyruleandresearch.nih.gov

Residency Research

- Many residency sites will not have access to IRB
  - Maintain your ethical responsibilities
  - Peer review
  - Go through the motions

- Ask yourself questions
  - Is my proposal and research ethical?
  - Are my subjects protected?
  - Are my subjects properly informed?
  - Do the subjects understand their rights & responsibilities?
  - Have I avoided coercion?
  - Have I asked them to sign a consent form?

Residency Research



NCOPE

Resident Directed Study
Statement Form

With submission of my *Directed Study* to NCOPE I agree that:

- I have met with all legal requirements, and if an IRB approval is required, it has been obtained
- Informed written consent has been obtained by all human subjects
- All HIPAA requirements have been met
- I have not participated in scientific misconduct (i.e., plagiarism). Plagiarism as defined by Benos, et al., 2005 is "using someone else's words, ideas, or results without attribution."

Resident Signature: _____

Date: _____

NCOPE
[illegible]

Effective January 2, 2007

Administrative Elements

Personnel, Budget, Timeline, & Resources

Personnel

Personnel

- Description of the research team
  - Primary investigator/researcher
  - Clinical support
  - Other key personnel or collaborators
- Qualifications
  - Brief resume or CV (curriculum vitae)
  - Experience/success with funding
  - Publication record
- Letters of support
  - Usually from collaborators
- Residency Project
  - Cite a brief background for yourself
  - Note other personnel needed (if required)

Resources

Resources

- Description of resources at your disposal
  - Facility description
    - Number of practitioners, technicians, support staff
  - Clinical resources
    - Fabrication
    - Fitting rooms
    - Assessment areas
  - Equipment
    - Gait lab
    - Testing equipment
    - Computer resources
- Residency proposal
  - Give a description of your *required or desired* resources

Budget

Budget

- Detailed break-down of project costs
- Critical step
  - Often difficult to change after approval
- Key expenses (i.e. "Direct costs")
  - Personnel
  - Equipment
  - Supplies (Other)
  - Travel
- Administrative costs (i.e. "Indirect costs")
  - Rent, electricity, facilities, support personnel
  - Usually a percentage of direct costs

Residency Research Budget

- Budget summary
  - Personnel
    - Time (% effort over study period)
    - Cost (% Salary, hourly wage)
  - Equipment
    - Computer, gait lab, prosthetic components
    - > $300
  - Supplies and Other
    - Questionnaires, copying, consumable materials, subject fees
    - < $300
- Budget justification
  - 1-2 paragraph explanation of budget summary

Example

Budget Summary:

Personnel		
Investigator – BJ Hafner (10% effort)	$	NR
Advisor – MR Owner (10 hours)	$	NR
Administrative Asst – MR Frontdesk (20 hours)	$	NR
Equipment		
Gait Lab Rental Fee (6 total hours at $50/hr)	$	300
Computer/Monitor/Data Backup Device	$	NR
Test Socket	$	150
SACH foot	$	240
Flex-Foot	$	Billed
Supplies		
Copy Fees	$	10
Total Funding Requested	**$**	**700**

Note: NR = Not Required/Requested

Timeline

Timeline

- Timeline is a phase or task-specific schedule
- Two types
  - Simple timeline – highlight study phases
  - Detailed timeline – note specific tasks/milestones
- Timeline should mirror methodology/procedures
- Useful for assessing feasibility
  - Sets deadlines
  - Compliments budget/resources
  - Track progress

Example – Simple Timeline

Phase	Description	Timeline (month)											
		1	2	3	4	5	6	7	8	9	10	11	12
1	Recruitment/Enrollment												
2	Baseline Data Collection (A)												
3	Intervention Data Collection (B)												
4	Baseline Data Collection (A)												
5	Data Analysis												
6	Final Report												

Example – Detailed Timeline

Task	Description	Timeline (Months)											
		1	2	3	4	5	6	7	8	9	10	11	12
1	Obtain IRB Approval												
2	Recruit Subject												
3	Enroll Subject												
4	Baseline Measurement 1												
5	Baseline Measurement 2												
6	Baseline Measurement 3												
7	Baseline Measurement 4												
8	Baseline Measurement 5												
9	Apply Intervention												
10	Accommodation Period												
11	Intervention Measurment 1												
12	Intervention Measurment 2												
13	Intervention Measurment 3												
14	Intervention Measurment 4												
15	Intervention Measurment 5												
16	Remove Intervention												
17	Accommodation Period												
18	Baseline Measurement 1												
19	Baseline Measurement 2												
20	Baseline Measurement 3												
21	Baseline Measurement 4												
22	Baseline Measurement 5												
23	Statistical Analysis												
24	Draft Report												
25	Turn in Final Report												

☐ = work phase ☐ = milestone

Questions?

For Next Week

- Lecture
  - Data Analysis and Statistics
- Assignment
  - Continue drafting research proposal
  - Plan class discussion
  - Meet with peers / instructors to develop ideas, as needed