RESEARCH

**IRB, Departmental Requirements & Resources**

- Preliminary discussion of IRB & HIPAA
- Education requirements for research component of residency
- Research resources & Funding
Human Subject Oversight and Clinical Research

More than just a pain in the #!@&^*(%$#
Federal Oversight of Human Subject Research Policies

- **Policies** apply to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.

- **The Common Rule**
  - Review of research by IRB
  - Requires informed consent of subject
  - Institutional assurances of compliance

- **Code of Federal Regulations**
  - [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)
IRB review must consider:

- The balance of:
  - **Risks** to the subjects
  - *versus*
  - Anticipated **benefits** to subjects and others

- Importance of knowledge that might be gained

- Informed consent process to be utilized
Some groups which have characteristics making them uniquely vulnerable

- **Children**
  - Can’t put children at risk without benefit (i.e. placebo)

- **Prisoners**
  - No consideration for sentence

- **Pregnant Women & fetuses**
  - Preclinical animal studies where feasible
  - Intervention may benefit fetus/mother OR risk is minimal

- **Cognitively Impaired**
  - Understanding of study and legal consent
The Office for Civil Rights enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information.

The HIPAA Security Rule, which sets national standards for the security of electronic protected health information (PHI).

The Privacy Rule provides federal protections for PHI.

- gives patients an array of rights with respect to that information.
- At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes.
Protected Health Information (PHI) - ANY of the following

- name,
- address
- city, county, precinct, zip code
- all elements of dates (except year) directly linked to an individual (birth date, admission date, discharge date, date of death)
- telephone number, fax number, e-mail address
- social security number, medical record number, health plan beneficiary number
- account number
- certificate/license number
- vehicle identifiers, device identifiers
- Web Universal Resource Locators, Internet Protocol address numbers
- biometric identifiers including finger or voice prints
- full face photographs and comparable images
- and any other unique identifying number, characteristic or code
Three Levels of Review

- **Exempt (minimal risk)**
  - No recording of personal health information (PHI)

- **Expedited (minimal risk)**
  - Limited PHI maintained for tracking

- **Full Board Review**
  - May be greater than minimal risk
Exempt Categories

1. Research of normal educational practices
2. Research involving educational tests, surveys, interviews or observation of public behavior
3. Research involving educational tests...
4. Research involving the study of existing data, documents, records, pathological or diagnostic specimens
5. Research conducted by or subject to the approval of federal Department or Agency heads
6. Taste and food quality evaluation or consumer acceptance studies
Exempt Category

- Information obtained must be recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects

AND

- Any disclosure of the human subjects' responses outside the research cannot reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation
Expediting Categories
(minimal risk only)

1. Clinical studies of drugs or devices when an IND or IDE is not required
2. Collection of blood samples by finger stick, heel stick or venipuncture
3. Prospective collection of biologic specimens for research purposes by noninvasive means
4. Collection of data through noninvasive procedures; e.g. MRI, EKG, etc.
5. Research involving materials that have been collected or will be collected for non-research purposes (i.e. clinical standard of care)
6. Collection of data from voice, video, digital or image recordings
7. Research on individual or group characteristics or behavior
8. Continuing review of research previously approved by a convened IRB when the study is closed to further enrollment
9. Continuing review of research not conducted under an IND or IDE
Elements of Consent (8)

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm

1. A statement that the study involves research
   - explanation of the purposes of the research
   - expected duration of the subject's participation
   - description of the procedures to be followed
   - Standard of care VERSUS experimental.

2. A description of any reasonably foreseeable risks or discomforts

3. A description of any benefits

4. A disclosure of appropriate alternative procedures or courses of treatment

5. A statement describing how records will be kept confidential and who will be allowed to inspect those records (i.e. HIPAA)
Elements of Consent

6. If more than minimal risk
   - is there any compensation
   - are medical treatments available if injury occurs and, if so, what they consist of

7. An explanation of whom to contact for answers to pertinent questions

8. A statement that participation is voluntary
   - refusal to participate will involve no penalty or loss of benefits
   - subject may discontinue participation at any time without penalty or loss of benefits
Additional elements to be included when appropriate

1) Statement: particular treatment or procedure may involve unforeseeable/unknown risks

2) subject's participation may be terminated by the investigator without regard to the subject's consent;

3) Any additional costs due to participation in research;

4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5) statement: significant new findings which may relate to the subject's willingness to continue participation will be provided

6) The approximate number of subjects involved in the study both locally and nationally/internationally.
Waiver of Consent

IRB may approve a consent procedure which does not include, or alters, some elements of informed consent

OR waive the requirements to obtain informed consent provided the IRB finds and documents that:

1) The research involves no more than minimal risk to subjects

2) The waiver or alteration will not adversely affect the rights and welfare of the subjects

3) The research could not practicably be carried out without the waiver or alteration; and

4)Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Research Education Requirements
Goals for Resident Education in Research

- Provide an understanding of the process in order to gain a perspective in academic medicine
  - *Not to make research scientists out of you*

- Provide a background for continuing education
  - *Evaluation of new information that impacts your practice*
  - *Evidence based medicine*

- **Required by AAPM&R! 🙃**
Mandatory Research Requirements

- Completion of online CITI IRB and HIPAA courses
  - http://www.ucdenver.edu/academics/research/AboutUs/comirb/training/Pages/amc.aspx

- ALL research projects **MUST** be pre-approved
  - All projects must have a letter (email) from mentor

- ALL IRB submissions **MUST** be pre-reviewed
Useful Resources for Research and Education
Research Resources

- **Local**
  - Health Sciences Library (UCDenver)
    - [http://hslibrary.ucdenver.edu/](http://hslibrary.ucdenver.edu/) (need employee ID #)
    - **Many, Many databases available! Use it!**
  - TCH Medical Library
    - [http://www.thechildrenshospital.org/pro/](http://www.thechildrenshospital.org/pro/)
  - Departmental Web site
    - [http://www.ucdenver.edu/academics/colleges/medicalschool/departments/pmr/Pages/Welcome.aspx](http://www.ucdenver.edu/academics/colleges/medicalschool/departments/pmr/Pages/Welcome.aspx)
    - Login/password (pmr/pmr)
  - COMIRB (human subject oversight)
    - [http://www.ucdenver.edu/academics/research/AboutUs/comirb/Pages/comirb-home.aspx](http://www.ucdenver.edu/academics/research/AboutUs/comirb/Pages/comirb-home.aspx)
Research Resources

**Federal**

  - Many other resources: drug info, history of medicine, household product info, genetics for the lay person, etc.
  - Non prescription drug information

- **ClinicalTrials.gov**

- **NIH**

- **FDA**
  - [http://www.fda.gov/](http://www.fda.gov/)
Research Resources

- **Commercial**
  - Epocrates
  - Medscape/WebMD
    - [http://www.webmd.com/](http://www.webmd.com/) or at UC Denver Library
  - MDconsult (via library)
  - eMedicine (via library)
- **Cochrane Library (via library)**
  - First Consult (via library)
  - Harrisons online (via library)
Research Resources

- **Bibliographic software**
  - Endnote

- **Funding**
  - Pilot grants
    - CCTSI (at UCHSC and TCH)
      - i.e. Colorado Clinical & Translational Sciences Institute
    - Research Institute (TCH)
    - CTRC laboratory support for labs
  - Journal article reprints, endnote
  - Limited project expenditures
Helpful Tutorials

○ Evidence Based Medicine
  ● Introduction to Evidence Based Medicine
    ○ http://www.hsl.unc.edu/Services/Tutorials/ebm/index.htm
  ● Evidence Based Medicine tutorials
    ○ http://library.umassmed.edu/EBM/tutorials/index.cfm
  ● Evidence Based Medicine toolkit
    ○ http://www.ebm.med.ualberta.ca/

○ Evaluating the Medical Literature
  ● How to evaluate the literature: Students & Housestaff

○ Study Design
  ● Guide to Research Methods
    ○ http://library.downstate.edu/ebmdos/3ebm100.htm
  ● Clinical Trials
    ○ http://en.wikipedia.org/wiki/Clinical_trial
Evidence-Based Medicine

"Evidence-Based Medicine is ... a set of procedures, pre-appraised resources and information tools to assist practitioners to apply evidence from research in the care of individual patients." – K.A. McKibbon, McMaster University

Essential Resources

Use this list as you would a ladder, working your way from the top down. Look for best evidence first in Cochrane Database and if you can't find good evidence there, continue down the list, understanding that the farther down you travel, the weaker the evidence you will find.

• **Cochrane Database of Systematic Reviews** (Full-text) – Via Ovid. A collection of structured systematic reviews and protocols (which are systematic reviews in process). Often include meta-analysis (statistical analysis) in the form of visual "forest plots."
• **Cochrane Database of Systematic Reviews** (Browse only - no full text) – Use this site, hosted by The Cochrane Collaboration, to browse Cochrane Systematic Reviews by topic/Cochrane Review Group.
• **DynaMed** – Evidence-based clinical review summaries.
• **DARE (Database of Abstracts of Reviews of Effects)** – Abstracts of non-Cochrane systematic reviews.
• **ACP Journal Club** – Abstracts of articles containing strong evidence from within the primary literature.
• **U.S. Preventive Services Task Force** – Database of evidence-based recommendations in areas of prevention and screening.
• **PubMed Clinical Queries** – PubMed/MEDLINE search feature that filters results in order to display only articles backed by good evidence. NOTE: At the PubMed home page, choose the Clinical Queries option from the blue, left navigation bar under "PubMed Services."
• **National Guideline Clearinghouse** – Collection of guidelines from the federal government Agency for Healthcare Research and Quality (AHRQ) and professional medical societies.
• **TRIP Database** – An EBM search engine that searches across multiple Evidence-Based information sites. While not all findings are full-text, TRIP includes many unique resources such as "Bandolier" and guidelines not found through National Guideline Clearinghouse.
• **Natural Standard** – Graded evidence on complementary therapies.
• **eMedicine Clinical Knowledge Base** – Background narratives, often with emphasis on best-evidence outcomes, covering topics across the medical and surgical spectrum.
• **UpToDate** – Background narratives, often with emphasis on best-evidence with a special focus on internal medicine, family medicine, pediatrics and obstetrics and gynecology.

This site, a collaborative effort between the Lamar Soutter Library and the Department of Family Medicine and Community Health, was originally funded through the Medical School's Innovations in Medical Education Grants program.

Lamar Soutter Library, Univ. Mass. Medical School; [http://library.umassmed.edu/EBM/index.cfm](http://library.umassmed.edu/EBM/index.cfm)
Research Project Development

- Submit ideas using development form
- Once project concept has been identified submit more complete information on “Preparatory to Research” form
- Develop complete protocol and submit to COMIRB

All protocols MUST be reviewed prior to submission to any agency including COMIRB!!!!!!!
Research Talks for Graduating Residents

- Upcoming lecture on how to give a scientific talk in January to led off series
- Scheduled Wednesday talks in upcoming weeks leading up to Gersten day
  - Consider them works in progress
- All graduating PGY-4’s send me your title and an abstract of your research (300 words or less)
  - Schedule time with me in January!!!!!!
Go Forth and Celebrate!!!
Happy Holidays