


Human Subjects Protection in Research: An Overview and Case Studies




Mike Horst, PhD  
Research  
544-5999

### Objectives

- Outline the purpose of human subjects protection regulations and procedures
- Describe general procedures related to IRB approval and requirements for research
- Determine appropriate questions and course of action for sample case studies related to human subjects protection in research


### Anyone volunteering your child?

- A physician decides to test a new vaccine on children. He injects an 8 year old with a virus to determine if the child will develop an immunity to a similar virus.




### Result

- In 1796, Edward Jenner injected a healthy 8 year old with cowpox, then 3 months later with smallpox.
- Hailed as discoverer of smallpox vaccine.




### Ethical?

- Spanish immigrant workers are injected with the agent for yellow fever.
- They are paid \$100 to participate.
- If they contracted the disease, they were paid another \$100 (was payable to their family if they died).



### Result

- In 1900 -- Walter Reed did this in Cuba.



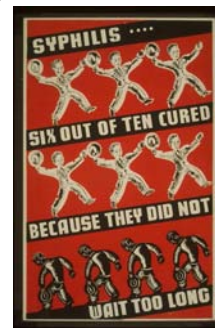
### Ethical?

- Deceptive advertising for “special free treatments” when no treatment was provided – subjects only went through a painful spinal tap and other examinations.
- Deliberate withholding of known therapies to study the progression of untreated disease (syphilis).

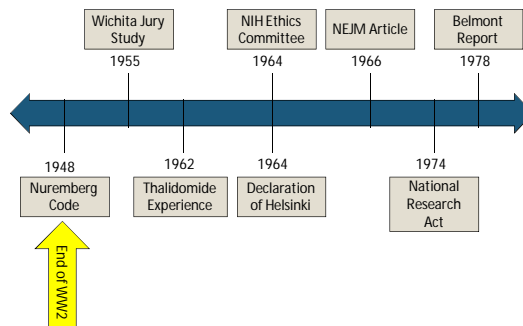


### Tuskegee

- 1932-1972: U.S. Public Health Service study in Tuskegee, Alabama of more than 400 black sharecroppers observed for the natural course of untreated syphilis.
- In 1947, penicillin was the standard therapy for syphilis.



### Historical Perspective (US): Human Subjects Protection



### Modern Day IRB Function


- Belmont Report (1978) identified 3 principles:
  - Respect for Persons: Individuals are autonomous agents and obligates the researcher to ensure that a participant enters into the research voluntarily and with adequate information
  - Beneficence: Human participants are treated in an ethical manner- respecting their decisions, protect from harm, and make efforts to secure their well-being – balance of potential risks and benefits
  - Justice: Equitable distribution of research burdens and benefits
- Including guidelines for
  - Obtaining informed consent
  - Respect for privacy and confidentiality
  - Risk/benefit assessment

### Federal Regulations

- HHS Regulation for the Protection of Human Subjects
  - 45 CFR Part 46
- Food and Drug Administration Regulations
  - 21 CFR Parts 50 and 56
- HIPAA


Established the IRB (Institutional Review Board) to provide oversight on all human subjects research to insure that it meets ethical standards.

So what does this mean for me?



### I have a project, what do I do next?

- Is the project research?
  - If yes, then it needs to come to the LG IRB
  - If no, then it does not need to come to the LG IRB
- How do I determine if it is research?




### What is "Research?"

- Federal Regulations define research as:
  - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.



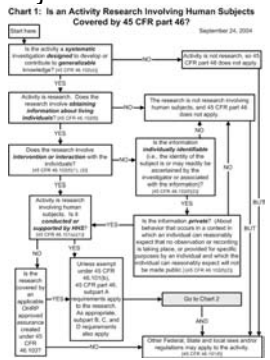
### Human Subjects

- Human subjects are defined as:
  - "living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information".

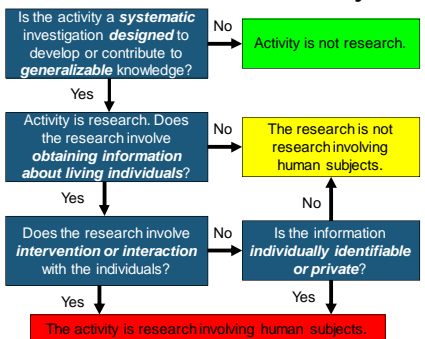


### When is it Human Subject Research?

- The Office for Human Research Protections (OHRP) provides guidance to help determine if an activity is research involving human subjects.
- <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>



### Research or involve human subjects?



### Research vs PI (Performance Improvement)

Is the activity a **systematic** investigation **designed** to develop or contribute to **generalizable** knowledge?

No → **Activity is not research.**

Yes → **The activity is research.**

- Intent or design
  - Research
    - Generalizable – populations/representative outside LG
    - Shared, published or presented outside LG
    - Partnerships/collaborations
  - PI
    - Understanding or making decisions about LG population only
    - LG internal use only
    - LG entities are the only participants

**The NEW ENGLAND JOURNAL OF MEDICINE**  
 DECEMBER 28, 2008

**An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU**

**Abstract**  
 Catheter-related bloodstream infections occurring in the intensive care unit (ICU) are common, costly, and potentially fatal. We conducted a collaborative cohort study predominantly in ICUs in 2007. An evidence-based intervention was used to reduce the incidence of catheter-related bloodstream infections. Multidisciplinary evidence-based practice was used to reduce catheter-related bloodstream infections, including, among others, implementation of the study intervention. Rates of infection per 1000 catheter-days were reduced at least monthly, according to the problem after the evidence-based intervention. Significant results.

### Catheter-related Blood Stream Infection Care Team Checklist

**Purpose:** To work as a team to decrease patient harm from catheter-related blood stream infections  
**When:** During all central venous or arterial line insertions or re-wires  
**By whom:** Include name

1. Today's date: month / day / year

2. Procedure:  New line  Rewire

3. Is the procedure:  Elective  Emergent

4. Before the procedure, did the healthcare staff:

	Yes	No	Don't know
Wash hands (with alcohol or soap) immediately prior	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sterilize procedure site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Drain entire patient in a sterile fashion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

During the procedure, did the healthcare staff:

	Yes	No	Don't know
Use sterile gloves	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use hat, mask and sterile gown	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Maintain a sterile field	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did all personnel assisting with procedure follow the above precautions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

After the procedure:

	Yes	No	Don't know
Was a sterile dressing applied to the site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please return completed form to the designated location in your ICU.

"The results were stunning. Within three months, the rate of bloodstream infections from these I.V. lines fell by two-thirds. The average I.C.U. cut its infection rate from 4 percent to zero. Over 18 months, the program saved more than 1,500 lives and nearly \$200 million."

### What do I need for LG IRB Review?

- Research protocol (investigator generated)
  - Research questions, methods, sample sizes and justification, instruments, data elements collected, investigators, etc.
- Research application (IRB form)
- Investigator disclosure forms (IRB form)
- Consent documentation
  - Consent form (investigator generated) or
  - Waiver of consent (IRB form)

Project Title: Validation of Spatial Scan Data from Syndromic Surveillance for Common Illnesses in the Lancaster Community

**Principal Investigator**  
 Michael A. Hogue, PhD, MPH, MS  
 Lancaster General Research Institute  
 1215 N. Duke Street  
 Lancaster, PA 17602  
 (717) 544-1000  
 mhogue@lancastergeneral.org

**A. Background and Significance**  
 With the recent increase in the use of Electronic Medical Records (EMR) in healthcare, data sources are used to aid in the study, detection and prevention of disease within communities. Paper-based charting systems relied upon manual extraction for use and analysis. But EMR systems provide significantly enhanced abilities to use this data to improve the health of communities. By capturing and analyzing common illnesses and diagnoses that are seen in healthcare settings, the health system can more effectively prepare for outbreaks and the public can be informed relative to the types and symptoms that are being observed to help identify when they should seek medical attention and how to manage their care at home.

Acute illnesses have a significant impact on primary care (family practice, ambulatory or internal medicine) offices and emergency rooms. These illnesses include acute upper respiratory infections (common colds) and gastrointestinal infections (fluores and vomiting). It is estimated that acute upper respiratory infections are the second most common diagnosis in physician offices and the most common for emergency rooms. Acute gastrointestinal infections are also commonly seen in family practice or emergency room settings. With the recent emphasis upon transparency and accountability, it is important to have better data to understand the impact of these common illnesses.

After reading this document, the IRB should know what the human subjects will experience, risks to the subjects, the justification/questions to be answered in the study and have confidence in the scientific validity/integrity of the study.


### THE LANCASTER GENERAL HOSPITAL APPLICATION FOR RESEARCH PROJECT

APPLICATIONS WHICH ARE INCOMPLETE OR HAVE MISSING SIGNATURES WILL BE RETURNED AND MAY BE RE-APPROVED BY THE INSTITUTIONAL REVIEW BOARD (IRB) AT THE DISCRETION OF THE IRB. APPLICATIONS MUST BE RECEIVED AT LEAST TWO WEEKS PRIOR TO THE SCHEDULED MEETING.

IS THIS PROJECT SUBMITTED FOR CONSIDERATION UNDER THE "COOPERATIVE AGREEMENT" BETWEEN LGH & LANIC?  YES  NO (IF YES, PLEASE PROVIDE COPIES OF ALL DOCUMENTS: HQ 2, YES [ ] )

1. DATE OF APPLICATION:
2. TITLE OF PROJECT:
3. PRINCIPAL INVESTIGATOR:
4. COLLABORATORS:
5. SPONSOR:
6. BRIEF SUMMARY AND OBJECTIVE OF THE PROJECT:

1. ESTIMATED DURATION OF THE PROJECT:
2. ESTIMATED NUMBER OF SUBJECTS TO BE ENROLLED: LGH site \_\_\_\_ Total \_\_\_\_
3. WILL THIS PROPOSED DRUG/DEVICE/PROCEDURE REPLACE AN EXISTING DRUG/DEVICE/PROCEDURE?  NO  YES (IF YES, ESTIMATE ANY EXPECTED COST INCREASE OR SAVINGS):
4. ARE THERE OTHER SIMILAR DEVICES/DRUGS/PROCEDURES (IN USE OR INVESTIGATIONAL)?  NO  YES (IF YES, ITEMIZE):



Leicester General Hospital  
Institutional Review Board  
Disclosure of Significant Financial Interest in Research Policy.

Before completing this form, please read the LGH IRB Conflicts of Interest in Research Policy.

Type of Disclosure:  New  Amendment to prior disclosure

Name of Person completing this Form: \_\_\_\_\_

Title of Protocol: \_\_\_\_\_

Relationship to Protocol (i.e., PI, sub-PI, etc.): \_\_\_\_\_

PI or Protocol of Affiliation from person completing this form: \_\_\_\_\_

1. Based on the definitions contained in the LGH IRB Conflicts in Research Policy, do you or any members of your family:

a. Receive consulting fees, honoraria (including honoraria from a third party, of the original source or a Financially Interested Business), gifts or other "in kind" compensation from a Financially Interested Business or institution to the same, whether for consulting, lecturing, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the prior calendar year exceeded \$10,000, or are expected to exceed that amount in the next twelve months? Yes \_\_\_ No \_\_\_

b. Have equity interests, including stock options, of any amount in a non-publicly-traded Financially Interested Business (as defined in the policy)? Yes \_\_\_ No \_\_\_

c. Receive equity interests (or entitlement to the same) in a publicly-traded Financially Interested Business that either exceed \$10,000 (when valued in reference to current public prices or using accepted valuation methods) or represent more than 1% ownership interest in any single entity? Yes \_\_\_ No \_\_\_


d. Receive royalty income or the right to receive future royalties under a patent license, copyright, or other agreement where the research is directly related to the licensed intellectual or work? Yes \_\_\_ No \_\_\_

e. Receive non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement). This includes, but is not limited to, honoraria for the investigator in excess of reasonable costs.

## Informed Consent


- To involve a human being; must have informed consent of the subject or the subject's legally authorized representative.
- Voluntary choice of an individual to participate in research based on purposes, procedures, risks, benefits, and alternatives
  - Full disclosure
  - Adequate comprehension
  - Voluntary choice to participate
- Can be waived
  - Could not practicably be carried out without waiver
  - No more than minimal risk
  - Not alter rights and welfare of subjects.

Consent is not just the completion of a "form" - it is a process.



CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

- STUDY TITLE:** [Specify as appears on study title page]
- PROTOCOL NUMBER & PROTOCOL DATE:**
- PRINCIPAL INVESTIGATOR AND COLLABORATORS:**  
To include names and phone numbers of all investigators and collaborators at Leicester General Hospital of "Cooperative Agreement" study; please include Leicester Regional Medical Center investigators and collaborators, as well.
- Include the following statement verbatim prior to the "Introduction" paragraph:  
Anyone who is asked to participate in a research trial of a new drug, device or medical treatment must give his or her consent prior to participating. In order to decide if you want to take part in the study, you need to understand the risks and benefits that are involved. The consent form you are about to read gives detailed information about this study. Once you understand the study, you will be asked to sign the consent form if you wish to participate. A signed copy of this consent form will be given to you for your records.
- INTRODUCTION:**  
To include statement that the study involves research or experimental procedures.
- STATEMENT OF PURPOSE:**  
Research objectives defined in lay person's terms using fourth-grade vocabulary.
- NUMBER OF SUBJECTS INVOLVED:**  
State the total number of subjects expected to be enrolled in the entire study and the number of LGH.
- PROCEDURE, DURATION OF PARTICIPATION, AND REQUIRED FOLLOWUP:**  
Describe in lay person's terms the protocol to be followed in the conduct of the research study, being certain to include a lay person's description of the procedure, the length of the study, the tests involved and visits to the doctor, and anything else involving the patient in terms of the study and follow-up.
- BENEFITS:**  
Describe benefits to the subject and/or to others, which may be reasonably expected.



RESEARCHER REQUEST FOR WAIVER OF THE RESEARCH INFORMED CONSENT AND AUTHORIZATION REQUIREMENT

Researcher Name: Last \_\_\_\_\_ First \_\_\_\_\_ MI \_\_\_\_\_

Phone Number: \_\_\_\_\_

Title of Project: \_\_\_\_\_

*This form must be completed by one researcher seeking a waiver of the research authorization requirements. The researcher completing this form should complete this form in its entirety and sign and date the form. PLEASE PRINT*

*In order for the IRB to grant a Waiver of the Consent and Authorization requirements, the IRB must be satisfied that the project involving one individual use or disclosure of PHI involves no more than minimal risk to the individual participants and all of the criteria listed below have been met. If Partial Waiver of HIPAA authorization may be granted if the use and disclosure is no more than minimal risk in the privacy of individuals and meets the minimum necessary. For example, a partial waiver could be used for recruitment purposes or for naming a specific part of the research, but not for the entire study.*

*I am applying for a waiver of the informed consent requirements.*

*In addition, I am applying for a waiver of the HIPAA authorization requirements:*

For the full study

A Partial waiver for:

Recruitment

Other \_\_\_\_\_

- Describe the proposed recruitment process. If a partial waiver for recruitment is not requested, enter "N/A" and skip to Question 2.
- What is the source of the PHI.
- What PHI or other information is to be extracted from the source above.

## HIPAA and Research

- Conditions that PHI may be used for research purposes - written authorization for use
  - PHI: name, address, DOB, phone, e-mail, SS#, MRN, other ID#'s, photos, dates of service (where a subject could potentially be identified) etc.
- Waiver from the authorization requirement in certain circumstances:
  - Activities preparatory to research;
  - Research on decedent's records;
  - When obtaining a subject's consent would be impracticable.

## Special Cases

- Protected classes (subjects)
  - Pregnant mothers and fetus, neonates, children, prisoners,** cognitatively impaired, emergency cases, terminally ill, elderly and high privacy risk (i.e. HIV)
- Educational research – often exempt
- Grad students
  - LG IRB approval is required for any LG study using LG data, patients, etc.
  - School may also require their own IRB review or accept LG IRB approval letter

## IRB Procedures

- Review
  - Initial
    - Full board review
    - Expedited review
    - Exemption – IRB reviewed study and determined as exempt
  - Continuing review – once approved, reviewed annually
  - Amendments – any changes
- IRB contact
  - Toni Phelan, IRB Coordinator
    - Ext. 45091
    - avphelan@lancastringeneral.org

PI needs to look for this notice!



## Case 1

- A study to determine predictive factors of CHF readmission within 30 days.
- Retrospective cohort study of all CHF admissions December 2008-March 2009.
- Data are abstracted from patient charts.

Lancaster General Health Data Collector: \_\_\_\_\_

**Factors Associated with Congestive Heart Failure Readmission**

1. Index Admit Account #:

2. Patient MRN:

3. Name:

4. Date of Birth:

5. Gender:

6. Date of Index Admission:

7. Date of Index Discharge:

**Severity:**

8. Street Address 1: \_\_\_\_\_

9. Street Address 2: \_\_\_\_\_

10. City: \_\_\_\_\_

11. State: \_\_\_\_\_

12. Lives alone upon admission/discharge?  Yes  No

13. Admit from SNF?  Yes  No

14. No CHF?  Yes  No

15. No MI, CAD, and Hypertension/Coronaryopathy (CCM)?  Yes  Verified  If absent from chart, record date value: \_\_\_\_\_

16. No Non-Ischemic Cardiomyopathy (NICM)?  Yes  Verified  If absent from chart, record date value: \_\_\_\_\_

17. Ejection Fraction (EF)  Yes  No  Verified  If absent from chart, record date value: \_\_\_\_\_

18. MI?  Yes  Verified  If absent from chart, record date value: \_\_\_\_\_

19. CCM?  Yes  Verified  If absent from chart, record date value: \_\_\_\_\_

20. Atrial Fibrillation?  Yes  Verified  If absent from chart, record date value: \_\_\_\_\_

21. No CVA?  Yes  Verified  If absent from chart, record date value: \_\_\_\_\_

CG Research Institute 6/22/2008 Page 1 of 2 CHF Readmission Factors

## Submit to IRB

- Research protocol (investigator generated)
  - Research questions, methods, sample sizes and justification, instruments, data elements collected, investigators, etc.
- Research application (IRB form)
- Investigator disclosure forms (IRB form)
- Consent documentation
  - Waiver of consent (IRB form)

Most likely an expedited IRB review.

## Case 2

- A prospective study to enroll moms who are pregnant with their first child
- Purpose: determine factors influencing family growth and health
- Multi-site study: coordinating site PSU College of Medicine (Hershey) and including LGH, Lehigh Valley, Reading, Pinnacle, York and Mount Nittany
- Phone interview prior to delivery (baseline), post-partum, 6, 12, 18, 24, 30 and 36 months. Chart review to collect data labor and delivery data
- Linked data by subject identifiers

Medical Record Abstract Form Participant ID#

**FIRST BABY STUDY**  
Delivery, Hospitalization, Medical Record Abstract Form

GREET  
Hello, My name is \_\_\_\_\_ May I speak with (NAME OF RESPONDENT)?

INTRO  
Hello, My name is \_\_\_\_\_ and I am calling from the Four State Center for Survey Research. We recently sent you a letter reminding you that we would be calling to conduct an interview as part of the First Baby Study. Today's interview will take about 20 minutes, and we will mail you a gift card in the amount of \$20 after the interview. May I begin the interview now? (CHECK/UNCHECK ANOTHER TIME IF NEEDED)

**A. Health of Mother**

A1. The first question is about your health now. In general, would you say your health is excellent, very good, good, fair, or poor?

EXCELLENT	1
VERY GOOD	2
GOOD	3
FAIR	4
POOR	5
DK	6
REF	7

A2. HEALTH PROBLEMS AND HEALTH CARE UTILIZATION OF MOTHER SINCE ONE-MONTH OVERVIEW

For the following questions please tell us about any **significant** health care you received specifically for any **respirations or serious health problems or events**, during the time period **from one last interview**, which was about one month after you had your baby, to **ONE MONTH BEFORE** AT APPROXIMATELY ONE YEAR POSTPARTUM.

A2. Have you had to go to the emergency room?

1. Yes  2. No  (If Yes, please describe the reason for your visit(s) and what services you received.)

3. No  
4. DK  
5. REF

6. Marital Status  
1. Married  
2. Single  
3. Divorced  
4. Widowed  
5. Missing

7. Race/Ethnicity  
1. White (Caucasian)  
2. Black (African-American)  
3. Hispanic  
4. Asian  
5. Other  
6. Missing

1. Participant ID#   
2. Abstractor ID#   
3. Hospital ID#   
4. Date of Admission Month  Day  Year   
5. Time of Admission Hour  Minutes   
6. Mother's date of birth: Month  Day  Year   
7. Marital Status  
1. Married  
2. Single  
3. Divorced  
4. Widowed  
5. Missing

## Submit to IRB

- Research protocol (investigator generated)
  - Research questions, methods, sample sizes and justification, instruments, data elements collected, investigators, etc.
- Research application (IRB form)
- Investigator disclosure forms (IRB form)
- Consent documentation
  - Consent form
- Be prepared to discuss vulnerable populations

Full IRB review.

## Case 3

- Goals:
  - Better understand current Interconception Care practices provided by family physicians within the context of well child visits
  - Assess the extent of specific maternal risk factors for recurrent preterm birth
  - Explore maternal attitudes and receptivity to receiving information about their own health in the context of their child's well child visit
- Methods
  - Anonymous survey of mother conducted at well child check
  - Multisite (LGH is coordinating site)

### Attachment #1 - Consent Form and Patient Questionnaire

Study ID: \_\_\_\_\_  
Abstractor ID: \_\_\_\_\_

**Mother's Health Care Needs During Well Child Visits Survey**

Your health center wants to find out how they can improve the health of mothers who bring their children in for well child visits. We are doing research to better understand the care mothers receive now from their baby's doctor and how they feel about that.

This is an anonymous survey about yourself, your health care, and how you feel about your baby's doctor during your health care. Your name or identifying information will not appear anywhere on this survey. The survey should take about 5-10 minutes.

Your participation is voluntary. This does not have to answer any questions. If you do not want to, if you choose not to participate in the survey, your health care and the health care of your baby will not be affected in any way. If you have any questions about the survey please feel free to call the Institutional Review Board at \_\_\_\_\_.

If you agree to complete the survey, please move to Question #1.

This survey will ask you questions about your health (not your child's) since the birth of your child until a survey the doctor today.

1. Why did you bring your child to the doctor today?  
 a. 12 month check up  
 b. 24 month check up

2. Your Age: \_\_\_\_\_

3. What category best described your race:  
 a. White  
 b. Black or African American  
 c. American Indian  
 d. Asian  
 e. Native Hawaiian or Other Pacific Islander  
 f. Other or Unknown

4. Are you Hispanic?  
 a. Yes  
 b. No

5. What type of health insurance do you have for yourself?  
 a. Government sponsored (Medicaid, Medicare, Family Health Plus, Medical Assistance, etc.)  
 b. Private insurance or insurance offered by your employer  
 c. No insurance (self pay)

6. Did you get pregnancy care from your child's doctor?  
 a. Yes  
 b. No

7. Do you and your child use the same doctor's office?  
 a. Yes  
 b. No

**Specific Proposed Intervention:**

- Family Planning:
  - Assess women for contraception use at WCV
  - Reinforce increased inter-pregnancy interval.
  - Contraception treatment or referral
- Depression Screening:
  - Screen all women at newborn's WCV
  - If positive, assess and refer
- Smoking
  - Assess smoking status at newborn's WCV
  - Provide Advice using the 5 A's
- Folic Acid Supplementation
  - Recommend folic acid supplementation at 6 week Postpartum visit
  - Assess folic acid use at newborn's WCV
  - Educate about folic acid

## Submit to IRB

- Research protocol (investigator generated)
  - Research questions, methods, sample sizes and justification, instruments, data elements collected, investigators, etc.
- Research application (IRB form)
- Investigator disclosure forms (IRB form)
- Consent documentation
  - Consent form
- Be prepared to discuss vulnerable populations

Full IRB review.

## Case 4

- To demonstrate that hourly patient rounding (using a defined protocol which addresses patient pain, elimination, environment and positioning) by nursing personnel (Registered Nurses and Patient Care Assistants) improves patient safety as measured by patient falls.
- Outcome measures: fall rates/patient days, rounding compliance and measures of inpatient similarities/risk factors.

### Study Design

- Pre vs. Post on 2 nursing units
- Outcome: falls/1,000 patient days
  - Adjusted for:
    - LOS
    - Patient acuity (Elixhauser comorbidity measures)
    - Age
    - Gender
    - Insurance mix

### Submit to IRB

- Nothing – this is a PI project
- But, if you do.....
  - Research protocol (investigator generated)
    - Research questions, methods, sample sizes and justification, instruments, data elements collected, investigators, etc.
  - Research application (IRB form)
  - Investigator disclosure forms (IRB form)
  - Consent documentation
    - Waiver of consent (IRB form)

Expedited review – exempt research study.

### Case 5

- Evaluation of the validity and reliability of the ERASE pain scale
  - Phase 1: Content Validity
    - Expert opinion – survey of nursing and physicians
  - Phase 2: Criterion Validity
    - Compared with 1-10 pain scale on verbal ICU patients
  - Phase 3: Construct Validity
    - Pre/post turning or ET suctioning measure on post-op thoracic patients
  - Phase 4: Reliability
    - Internal consistency and inter-rater reliability

ICU E.R.A.S.E. Scale										
Date:	Time:									
<b>Agitation/Vocalization</b>	1 - Calm/Quiet									
	2 - Restless/Fidgeting									
	3 - Anxious/Agitating									
	4 - Uncontrollable/Crying out									
<b>Facial Tension/Expression</b>	1 - Calm/No tension									
	2 - Slight tension									
	3 - Moderate tension/ Grimacing									
<b>Respiratory Response</b>	1 - Spontaneous/regular breathing									
	2 - Tachypnea									
	3 - Tachypnea with dyspnea									
	4 - Dyspnea with Diaphragmatic retractions									
<b>Muscle Tone/Movement</b>	1 - Relaxed or Normal tone									
	2 - Some Tension/Occasional movements									
	3 - Moderate tension/ frequent movements									
	4 - Extreme rigidity/ Thrashing									
<b>Autonomic Responses/Other</b>	(+1) - Elevated Heart Rate									
	(+1) - Elevated MAP									
	(+1) - Diaphoresis									
	(-1) - Tearing/Crying									
<b>Total:</b>										
<b>Last pain med administered (time):</b>										
<b>RV entries</b>										

### ICU E.R.A.S.E. Study Expert Opinion Survey

Please fill out the following survey and return to the CPC Mailbox by \_\_\_\_\_. Thank you for your time and input.

Please see the attached pain assessment tool then complete the survey below:

1. I am a \_\_\_\_\_ Physician  
 \_\_\_\_\_ RN

2. I have been practicing for \_\_\_\_\_ years.

3. Currently, at Lancaster General, a isolated/unresponsive patient's level of pain is accurately assessed and treated.

Strongly Agree    Agree    Neutral    Disagree    Strongly Disagree

4. Currently, at Lancaster General, a non-verbal/amented patient's level of pain is accurately assessed and treated.

Strongly Agree    Agree    Neutral    Disagree    Strongly Disagree

5. Having a standardized tool would help facilitate the assessment of pain in patients who are unable to effectively communicate their pain level using the 1-10 rating scale.

Strongly Agree    Agree    Neutral    Disagree    Strongly Disagree

6. Agitation/Vocalization is a measurable outward expression of pain.

Strongly Agree    Agree    Neutral    Disagree    Strongly Disagree

7. The Agitation/Vocalization category of the ERASE tool will accurately evaluate a patient's level of agitation due to pain.

Strongly Agree    Agree    Neutral    Disagree    Strongly Disagree

### Phase 1 Submit to IRB

- Research protocol (investigator generated)
  - Research questions, methods, sample sizes and justification, instruments, data elements collected, investigators, etc.
- Research application (IRB form)
- Investigator disclosure forms (IRB form)
- Consent documentation
  - Waiver of consent (IRB form)

Most likely an expedited IRB review.

### Phase 2 Submit to IRB

- Research protocol (investigator generated)
  - Research questions, methods, sample sizes and justification, instruments, data elements collected, investigators, etc.
- Research application (IRB form)
- Investigator disclosure forms (IRB form)
- Consent documentation
  - Waiver of consent (IRB form)
- Be prepared to discuss vulnerable populations

Full IRB review.

### Phase 3 Submit to IRB

- Research protocol (investigator generated)
  - Research questions, methods, sample sizes and justification, instruments, data elements collected, investigators, etc.
- Research application (IRB form)
- Investigator disclosure forms (IRB form)
- Consent documentation
  - Waiver of consent (IRB form)
- Be prepared to discuss vulnerable populations

Full IRB review.

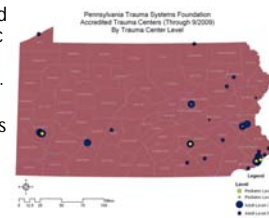
### Phase 4 Submit to IRB

- Research protocol (investigator generated)
  - Research questions, methods, sample sizes and justification, instruments, data elements collected, investigators, etc.
- Research application (IRB form)
- Investigator disclosure forms (IRB form)
- Consent documentation
  - Could be either.....
    - Waiver of consent (IRB form)
    - Consent form (nurses performing evaluations are also subjects)
- Be prepared to discuss vulnerable populations

Full IRB review.

### Case 6

- A study to identify what factors are most associated with VAP in post-traumatic hospital inpatients and create a risk scoring rubric.
- De-identified data from all 2005-2007 trauma patients (approx 80,000) from PTSF accredited sites.
- Data are electronically stored in the PTSF registry.



### Submit to IRB

- Research protocol (investigator generated)
  - Research questions, methods, sample sizes and justification, instruments, data elements collected, investigators, etc.
- Research application (IRB form)
- Investigator disclosure forms (IRB form)
- Consent documentation
  - Waiver of consent (IRB form)

Expedited review – exempt research study.