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Embedded in the IRB

Nancy Harger, MS LIS, RN
Judy Nordberg, MLIS

Lamar Soutter Library
University of Massachusetts Medical School

Ethics Day:
Engaging Librarians in the Responsible Conduct of Research
University of Massachusetts Amherst -- W.E.B. Du Bois Library
October 8, 2010
In a tragic situation that could have been averted, Ellen Roche, a healthy, 24-year-old volunteer in an asthma study at Johns Hopkins University, died in June because a chemical she inhaled led to the progressive failure of her lungs and kidneys. In the aftermath of this loss, it would appear that the researchers who conducted the experiment and the ethics panel that approved it allegedly overlooked numerous clues about the dangers of the chemical.

Adding particular poignancy to the published literature, the F.D.A. is conducting a "good-faith effort" to reexamine resources, including PubMed, however, with citations included in Sun's investigation included in the Tragedy.

Science

December 9, 1996

F.D.A. Officials Fault Penn Team in Gene Therapy Death

By Sheryl Gay Stolberg

ETHESDA, Md. — Officials of the Food and Drug Administration said Wednesday that Jesse Gelsinger, the 18-year-old Arizona man who lost his life in a gene therapy experiment in September, was ineligible for the clinical trial and should not have been treated because his liver was not functioning well enough before doctors infused him with a dose of corrective genes.
Timeline in the development of regulations on human-subjects research protections and institutional review boards (IRBs)

1932-1972, Tuskegee Syphilis Study

Late 1950’s, NIH CRC policy required Review of all research by Ethics Committee

1950’s, Willowbrook Hepatitis Studies

1955-1962, Thalidomide Use in Pregnant Women

1955, Wichita, KS Jury Deliberation Taping

1965, Dr. Beecher’s N Engl J Med article

1964, NIH requires Ethics Review Of all PHS-funded Research and World Med Assoc Declaration of Helsinki

1960’s, Jewish Chronic Disease Hospital Study

1974, Congress passes National Research Act; Start of Modern IRBs

1978, Belmont Report

1975-1978, National Commission Meetings

1981, Secretary of DHHS signs 45 CFR 46

1945

1955

1965

1975

1985

Fig. 1. Timeline in the development of regulations on human-subjects research protections and institutional review boards (IRBs). NIH = National Institutes of Health. CRC = Clinical Research Center. PHS = Public Health Service. DHHS = Department of Health and Human Services. CFR = Code of Federal Regulations.
The Study Begins

In 1932, the Public Health Service, working with the Tuskegee Institute, began a study to record the natural history of syphilis in hopes of justifying treatment programs for blacks. It was called the "Tuskegee Study of Untreated Syphilis in the Negro Male."

The study initially involved 600 black men – 399 with syphilis, 201 who did not have the disease. The study was conducted without the benefit of patients' informed consent. Researchers told the men they were being treated for "bad blood," a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness. In exchange for taking part in the study, the men received free medical exams, free meals, and bural insurance. Although originally projected to last 6 months, the study actually went on for 40 years.

What Went Wrong?

In July 1972, an Associated Press story about the Tuskegee Study caused a public outcry that led the Assistant Secretary for Health and Scientific Affairs to appoint an Ad Hoc Advisory Panel to review the study. The panel had nine members from the fields of medicine, law, religion, labor, education, health administration, and public affairs.

The panel found that the men had agreed freely to be examined and treated. However, there was no evidence that researchers had informed them of the study or its real purpose. In fact, the men had been misled and had not been given all the facts required to provide informed consent.
Tuskegee Experiment Scientist Spread Syphilis in Guatemala Too

Posted by David W Freeman

The government researcher who led the work in Guatemala, Dr. John Cutler, also was involved in this country's infamous Tuskegee experiment, where, from 1932 to 1972, scientists tracked 600 black men in Alabama who had syphilis but didn't know it, without ever offering them treatment.

"We are outraged that such reprehensible research could have occurred under the guise of public health," Secretary of State Hillary Rodham Clinton and Health and Human Services Secretary Kathleen Sebelius said today.

In Guatemala, 696 men and women were exposed to syphilis or in some cases gonorrhea, through jail visits by prostitutes or, when that did not infect enough people, by deliberately inoculating them, reported Susan Reverby, the Wellesley historian. Those who were infected were offered penicillin, but it was not clear how many were infected and how many were treated successfully.

(CNN) -- The Tuskegee syphilis experiment of the 20th century is often cited as the most famous example of unethical medical research. Now, evidence has emerged that it overlapped with a shorter study, also sponsored by U.S. government health agencies, in which human subjects were unknowingly being harmed by participating in an experiment.

Research from Wellesley College professor Susan Reverby has uncovered evidence of an experiment in Guatemala that infected people with sexually transmitted diseases in an effort to explore treatments.
Human Subjects: Institutional Review Board (IRB)

Welcome to the University of Massachusetts Medical School Institutional Review Board. If you plan to undertake in any research which uses human beings (patients, employees, general public), human medical data, or human specimens, the project must be reviewed and approved by the UMMS Institutional Review Board.

"Institutional Review Board" is a generic term, the board has different names at different institutions. Here at UMMS it is called the Committee for the Protection of Human Subjects in Research.

When you are ready to design a research project, you should obtain a copy of the Guidelines for the Preparation of Protocols for Review by the Committee for the Protection of Human Subjects in Research. These detailed instructions are available from the Research Subjects Office, 6-4261. The Research Subjects Office will also answer any questions you may have about the process.

http://www.umassmed.edu/subjects/human/index.aspx
Committee One

UMass Medical School IRB Identifier #00000269

1. Brian O'Sullivan, M.D., IRB Chair, Department of Pediatrics
2. Lucie Lajeunesse, B.S., IRB Vice Chair, Pharmacy
3. Diane Blake, M.D., IRB Vice Chair Department of Pediatrics
4. Alan Birnbaum, Ph.D. Community Health Link
5. Judy Nordberg, Library Information Service
6. Christopher Keuker, M.D. Pediatric Oncology
7. Albert Grudzinskas, Jr., J.D.
8. Richard Perugini, M.D. Surgery
9. Judith Savageau, MPH Family Community Medicine
10. Ginger Mangolds, N.P. Emergency Medicine
11. Susan Sullivan-Bolyai, Ph.D. Graduate School of Nursing
12. Paul Plasky, M.D. Psychiatry
13. Shayne Deal, Human Subjects Office
14. Michele Gadoua, Unaffiliated Community Member
15. Michael Centola, MHS, CIP, Human Subjects Office
16. Muthalagu Ramanathan, M.D. Division of Hematology/Oncology
17. Matthew Juhascik, Ph.D. Forensic Toxicology
18. James Chesbro, M.D. Cardiovascular Medicine
19. Alternate Member-Danielle Pichette for Shayne Deal

Committee Two

UMass Medical School IRB Identifier #00000270

1. Brian O'Sullivan, M.D., IRB Chair, Department of Pediatrics
2. Lucie Lajeunesse, B.S., IRB Vice Chair, Pharmacy
3. Roger Luckmann, M.D., IRB Vice Chair, Family & Community Medicine
4. Robert Carey, Ph.D. Psychology
5. Danielle Pichette, Human Subjects Office
6. Nancy Harger, R.N. Library Information Service
7. Carol Bova, Ph.D. Graduate School of Nursing
8. Wahid Wassef, M.D. Digestive Disease
9. Richard Wilson, Unaffiliated
10. Judith Savageau, MPH Family Community Medicine
11. John McCullough, Ph.D. Pharmacology/Molecular Biology
12. Stuart Levitz, M.D. Infectious Disease
13. Daniel Libraty, M.D. Center for Infectious Disease Vaccine Research
14. David Blehar, M.D. Emergency Medicine
15. Sherry Pagoto, Ph.D. Preventive Behavioral Medicine
17. Lance Lichtor, M.D. Department of Pediatrics/Anesthesiology
18. Christopher Rosenbaum, M.D. Emergency Medicine
19. Alternate Member-Shayne Deal for Danielle Pichette

CITI Collaborative Institutional Training Initiative

Welcome

CITI Login and Registration Page

The CITI Program is a subscription service providing research ethics education to all members of the research community. To participate fully, learners must be affiliated with a CITI participating organization.

The CITI course is a protected site. If you are a new learner at a participating organization you must register to create your own username and password and gain access to the site.

New Users Register Here
Principal investigator (PI) develops research protocol for submission. (For research conducted at HPD, follow HPD research guidelines.)

Submit to:

Center representative conducts initial review

For research conducted at HPD, submit to HPD Research Committee (required prior to any further IRB review)

Reviewed by HPD Research Committee, which forwards submission and required copies to IRB

Decision: Requires review

Forward to:

Office of Grants and Contracts

IRB staff member logs submission

IRB chair conducts initial review for either:

- Expedited review
- Full review

Decision communicated to PI and recorded

IRB reviews full review protocols

Office of Grants and Contracts maintains records

For funded projects: Office of Grants and Contracts notifies funding agency of IRB approval

HHS Decision Charts:
http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c2

PROTOCOL PROCESS
Flowchart
Nova Southeastern University (Florida) IRB
http://www.nova.edu/irb/forms/IRBChart.pdf
Responsible Literature Searching for Research: A Self-Paced Interactive Educational Program is an online education module to teach researchers the fundamentals of responsible literature searching for research practice.

To access the module, go to "Responsible Literature Searching" on the University of Pittsburgh's "Internet-based Studies in Education and Research" site. To view the module content, click on the "Powered by HSConnect icon" in the upper right corner and follow the directions to create your free access account.

Completion of this module is highly recommended for individuals involved in human subject research. It provides clinical researchers with knowledge of how to locate scientific literature to enable design of scientifically sound research studies, and to protect human subjects from harm.

The program provides a framework, instruction, and guidelines on:

1. accepted practices and principles associated with the biomedical literature search process,
2. identification and use of major information resources,
3. the role of reference librarians in the literature search process,
4. the limitations of information resources, and
5. determining what is an adequate literature search for topics such as drug safety and identification of adverse events.
EXEMPT REVIEW

Creation of a LibGuide for the Department of Emergency Medicine

http://libraryguides.umassmed.edu/EM_Guide
Improving Orthopedic Outcomes through a National Total Joint Replacement Registry

With $12 million grant, UMMS will lead nationwide study of joint replacement surgery outcomes

September 27, 2010

by: Alison Duffy, UMass Medical School Communications

Each year, more than 700,000 adults in the United States have knee or hip replacement surgery to eliminate what can often be debilitating pain, and regain joint function and mobility lost to advanced arthritis. With that number expected to grow significantly in the next 20 years, both for older adults and patients under age 65, accurately assessing the surgery’s real, everyday quality-of-life improvements for patients becomes critically important.

The Agency for Healthcare Research and Quality (AHRQ) has awarded the University of Massachusetts Medical School a $12 million grant to begin making these important assessments. As part of an in-depth study of key factors related to total joint replacement (TJR) surgery,

UMMS will establish a nationwide registry of 33,000 TJR patients, develop tools with which to assess the success and failure of the surgery, and conduct research to guide both clinical care and health care policy.

Arthritis is a significant public health issue, with 60 million U.S. adults diagnosed with osteoarthritis, a degenerative condition of joint

A Multicenter, Randomized, Double-Blind, Phase 3 Study of Ramucirumab (IMC-1121B) Drug Product and Best Supportive Care (BSC) Versus Placebo and BSC as Second-Line Treatment in Patient with Hepatocellular Carcinoma Following First-Line Therapy with Sorafenib.

Searching process in support of reviewers

- Review protocol to understand purpose of the research (terminology, search term ideas)
- Read the Consent form(s) for comprehension level
- Examine references provided in the protocol
- Do original search in PubMed and other databases on topic, drug or device to see what might be new
- Try preformulated search ‘hedge’ with drug name
  "treatment outcome" OR treatment outcome[mh] OR "fatal outcome" OR fatal outcome[mh] OR fatal OR "risk factors" OR "risk factor" OR risk factors[mh] OR death OR mortality OR "adverse drug reaction" OR safety OR drug toxicity[mh] OR "drug toxicity"
ELLIPSE™ Posterior Occipito-Cervico-Thoracic Stabilization System

The ELLIPSE™ System is a comprehensive, easy-to-use solution for the toughest of cases. The implants are designed to eliminate the fiddle factor associated with posterior OCT fusion for easier construct assembly. A wide range of instruments, including flexible and jointed occipital instruments, assist in swift installations of the implants. Features below are the highlights of "A Revolution in OCT Surgery."

- ElliptiClick™
  - Drop, Click & Lock
  - Rod retention feature retains the rod screw head to stabilize the construct.

- Non-Threaded Locking Cap
  - Robust design that eliminates over and directs set screw forces away from rod, unlike threaded systems which radially attack the screw head.

- Novel Instrumentation
  - Refined instrumentation from an access screwdriver, to the flexible, jointed occipital instrumentation, ensures construct assembly.

VIP™ (Vertical In Line Plate)

The VIP™ plating system is the low impact solution.

The plate's narrow width allows for a small, button-hole incision and less retraction compared to standard ACDF plating solutions. A larger diameter screw and single continuous bone interface ridge provides secure stabilization while achieving the fundamental purpose of the plate which is to secure the bone graft.

- Low Impact ACDF: Narrow, 10mm width may be inserted through a small incision and require less retraction.

Recurring leg and back pain is among the most common reasons for doctor visits in the U.S. For many, this pain is due to Lumbar Spinal Stenosis, a condition where the bones and soft tissue of the lower spine put pressure on spinal nerves. This pressure can cause pain, tingling, or numbness in the legs and lower back.

If you suffer from Lumbar Spinal Stenosis and have not received adequate relief with medications or physical therapy, you may qualify for a clinical research study. The study is evaluating the ACADIA™ Facet Replacement System, an investigational procedure that may relieve leg and back pain, as well as restore motion and stability to the lower spine. To learn more about the ACADIA Facet Replacement System, and see whether this study is right for you, please click here.

http://www.stenosisrelief.com/
Librarian Participation

- Send email with citations, pdfs, other supplemental information to reviewers in advance of committee meeting
- Attend monthly committee meeting
- Two reviewers summarize and present protocol
- All members participate in discussion of each protocol
- Use laptop to search at meeting if requested
- Participate in full vote to approve, approve with revisions or table protocol
- Follow up with searches as requested
Opportunities for librarians

- Some librarians serve as protocol reviewers on their IRBs
- Some are voting members, some are not
- Participation on the IRB enhances the work we do in other areas – outreach, networking, refined search skills, awareness of the process of clinical trial approval
- Some librarians may do literature searches for the PIs in preparation of protocol
- Volunteer position – do you have time in your workload?
- Would this role enhance the missions of your institution and of your library?
Thank you

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