University of Pittsburgh | Department of Anesthesiology and Perioperative Medicine

# RESEARCH

Observational Clinical Studies and IRB

# How to Perform an Observational Clinical Study

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# Retrospective Chart Review

- Scott the CA-2
- A case of hand transplantation
- Five hand transplants at UPMC

# Question

Is any IRB approval required?

# YES

because a retrospective chart review is research

# Institutional Review Board

- University of Pittsburgh Institutional Review Board (IRB) reviews UPMC and Pitt research
  - Unless industry-sponsored
- http://www.irb.pitt.edu/
  - Click PittPRO and login
  - submit your IRB

# Three Types of IRB Submissions

- **EXEMPT**
- **EXPEDITED**
- **FULL BOARD**

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  - de-identified chart review
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# Question

What research module does Scott have to pass to submit his IRB?

# Research Modules Necessary to Access OSIRIS

## CITI - http://www.citi.pitt.edu

**Refer to the CITI Instruction Sheet for how to navigate -**
**http://www.irb.pitt.edu/corpus/files/citi/CITI%20Instruction%20Sheet.pdf**

| Collaborative Institutional Training Institute (CITI) Program | |
|---|---|
| **Courses** | **Explanation of requirement** |
| CITI Basic Human Subjects Protection Training Program<br><br>CITI Responsible Conduct of Research (RCR) Training Program | **Required** for all individuals conducting human subject research<br><br>Re-certification will be required every 3 years and a CITI 'Refresher Course' will be available at that time |

Scott's research mentor has provided him with the list of the patients.

## Question

Where should Scott store the data with patients' identifiers?

# HIPAA

**The Health Insurance Portability and Accountability Act (HIPPA) of 1996**

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## HIPAA Breach

*Data Breach Results in $4.8 Million HIPAA Settlements*

*New York and Presbyterian Hospital - $3.3 Million*
*Columbia University - $1.5 Million*

*NYP/CU impermissibly disclosed the ePHI of 6,800 patients to Google and other Internet search engines.*

http://www.ihealthbeat.org/articles/2013/8/26/advocate-medical-group-reports-biggest-hipaa-breach-in-hhs-history

# HIPAA Breach Prevention

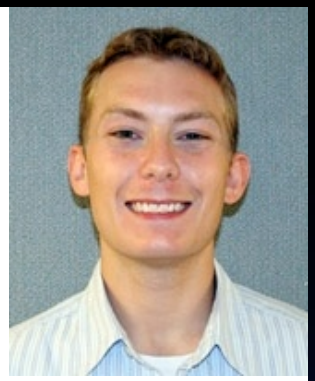
- **Keep data on UPMC network**
- If flash drive must be used, data must be de-identified or encrypted.

General Articles

SPECIAL ARTICLE

CME

# Anesthetic Management in Upper Extremity Transplantation: The Pittsburgh Experience



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**BACKGROUND:** Hand/forearm/arm transplants are vascularized composite allografts, which, unlike solid organs, are composed of multiple tissues including skin, muscle, tendons, vessels, nerves, lymph nodes, bone, and bone marrow. Over the past decade, 26 upper extremity transplantations were performed in the United States. The University of Pittsburgh Medical Center has the largest single center experience with 8 hand/forearm transplantations performed in 5 recipients between January 2008 and September 2010. Anesthetic management in the emerging field of upper extremity transplants must address protocol and procedure-specific considerations related to the role of regional blocks, effects of immunosuppressive drugs during transplant surgery, fluid and hemodynamic management in the microsurgical setting, and rigorous intraoperative monitoring during these often protracted procedures.

**METHODS:** For the first time, we outline salient aspects of upper extremity transplant anesthesia based on our experience with 5 patients. We highlight the importance of minimizing intraoperative vasopressors and improving fluid management and blood product use.

**RESULTS:** Our approach reduced the incidence of perioperative bleeding requiring re-exploration or hemostasis and shortened in-hospital and intensive care unit stay. Functional, immunologic and graft survival outcomes have been highly encouraging in all patients.

**CONCLUSIONS:** Further experience is required for validation or standardization of specific anesthetic protocols. Meanwhile, our recommendations are intended as pertinent guidelines for centers performing these novel procedures. (Anesth Analg 2012;115:678–88)

Lang RS, et al. Anesth Analg. 2012 Sep;115(3):678-88.