

L541 Lab Session

Week 4

February 2/3, 2012

Outline

- Human Subjects Research
- Cardinal Vowels
- Group Exercise
- Homework

Human Subjects Research

- IU Office of Research Administration
 - <http://researchadmin.iu.edu/cs-humsub.html>
- Human Subjects/IRB
 - Protect rights and welfare of human research participants
 - Create awareness and educate researchers about the rights and welfare of human research participants and about the ethical principles and federal regulations guiding research with humans.
 - Review and approve of all research involving human subjects and to ensure compliance with applicable University and organizational policies and federal regulations.



Below are the six basic steps to fulfill the Indiana University Research with Human Subjects requirements:



1. Does your study require IRB review?

Review the checklist to determine if the IRB needs to review your activity.

[Learn more >](#)

2. Pre Submission

- CITI completion
- Conflict of Interest
- Acknowledgement

[Learn more >](#)

3. Types of Review

Determine your review type and what **forms** are necessary.

[Learn more >](#)

4. Submission to the IRB

Determine how and when to submit.

[Learn more >](#)

5. Ongoing Actions Post Approval

- Continuing Reviews
- Amendments
- Unanticipated Problems
- Noncompliance
- Co-Investigator Updates

[Learn more >](#)

6. Close Out Study

Determine when your study can be closed with the IRB, what needs to be done to close your study, and what closing your study means.


[Learn more >](#)



Pre Submission Investigator Requirements

Upon reviewing the [Checklist for IRB Review](#) and determining that the IRB needs to review your activity, Principal Investigators and Co-investigators must complete each of the following **three** tasks before approval of a research study can be granted:

1. Complete the required Collaborative Institutional Training Initiative (CITI) modules

All principal investigators, co-investigators, (anyone involved in the design, conduct, or reporting of the research, or having significant interaction with subjects) including personnel obtaining informed consent listed on the IU IRB application will need to complete CITI training. CITI is a web-based tutorial and testing site that is frequently updated to reflect changes in human subject law and regulation. Additionally, CITI meets the  [Federal Requirement](#) that researchers using human subjects demonstrate the completion of education in the protection of human research participants.

2. Complete the Research-Related Financial Interest Disclosure Form

3. Provide agreements to participate in the research

All co-investigators and faculty sponsors listed on a research study must provide acknowledgement of their participation. This requirement can be fulfilled by including an e-mail from each individual with the submission.



Human Subjects Tool kit

Links:

- ▶ [Access to Collaborative Institutional Training Initiative \(CITI\)](#)
- ▶ [Checklist for IRB Review](#)
- ▶ [Common Rule](#)
- ▶ [Submission Process](#)
- ▶ [Definitions](#)

CITI Training

Certification Requirement:

Education on the Protection of Human Research Participants

As of October 1, 2000, the National Institutes of Health (NIH) requires researchers with NIH funding to have institutional certification of educational training with respect to the use of human subjects in research. Indiana University has adopted the use of Collaborative Institutional Training Initiative (CITI), a web-based tutorial and testing site offering education modules on the basic principles and procedures related to the protection of human research subjects.



- **Which Course do I take?**

Guidance on which CITI course to complete is located in the 'Tool kit' to the right.

■ **Take the Test**

[Click Here to begin Collaborative Institutional Training Initiative \(CITI\)](#)

Announcement:

New Human Subjects Research Education Requirement: Collaborative Institutional Training Initiative (CITI)

The Office of Research Administration (ORA) and the IRB Executive Committee are pleased to announce that the IU Institutional Review Board (IRB) will begin using the educational programs of the Collaborative Institutional Training Initiative (CITI) to meet the educational requirements for conducting research with human subjects effective October 1, 2010. [Read full announcement >](#)

A logo for the "Human Subjects Tool kit" with a dark background and white text.

- ▣ Guidance on which CITI course to complete
- ▶ CITI FAQs
- ▣ NIH Education Requirement
- NIH Human Subjects Education Documentation Form
- 📄.rtf 📄.doc **Tech Tip!**

**Social/Behavioral
Researchers
Stage 1
CITI Course**

CITI Training

- A web based training program in human subjects protections
- Course containing several modules, which include reading material that can be read on screen or printed and a brief online quiz covering the material.

Homework

- You have four weeks to complete the CITI training
- March 1/2
- Proof: When you've completed the course, a certificate will be issued as confirmation that you've finished the CITI training. Send me a copy of your certificate!

Cardinal Vowels

- Daniel Jones' Cardinal Vowels
 - <http://www.phonetics.ucla.edu/course/chapter9/cardinal/cardinal.html>
 - http://www.let.uu.nl/~audiufon/data/e_cardinal_vowels.html
 - <http://www.youtube.com/watch?v=6UIAe4p2I74>

Vowel Practice

Group Exercise

- Transcribe British English & American English words
- Compare sounds
 - Useful tools
 - IPA chart, with fonts:
<http://weston.ruter.net/projects/ipa-chart/view/keyboard/>
 - Clickable IPA chart (audio):
<http://www.phonetics.ucla.edu/course/chapter1/chapter1.html>
 - Terrin's recordings

Homework