



JOHNS HOPKINS

INSTITUTE *for* CLINICAL &  
TRANSLATIONAL RESEARCH

The Importance of Continued Research Training &  
Available Resources at Johns Hopkins

# Regulatory Changes in Clinical Research

- 2016
  - Changes to the electronic data submission for New Drug Applications, Abbreviated New Drug Applications, Biologics License Applications, and Investigational New Drug Applications
- 2017
  - Good Clinical Practice (GCP) Training required for all NIH funded Clinical Trials.
  - Expansion of Federal requirements to register clinical trials at ClinicalTrials.gov
- 2019
  - Effective Jan 21, 2019 all new federally funded human subjects research studies must comply with the revised Common Rule. (Expansion of the number of Exempt categories, new Key elements section in the Informed Consent, and changing of continuing review requirements)
  - Coming in 2020 Requirement to use a single IRB



# Competencies

- 2014 the Joint Task Force (JTF) published Harmonized Core Competency Framework for the Clinical Research Professional
- Clinical research institutions worldwide have adapted the framework to develop job descriptions, training modules, and other resources
- 2017 Version 2.0 of the Competency Framework was released



# Differences Between Children and Adults as Learners

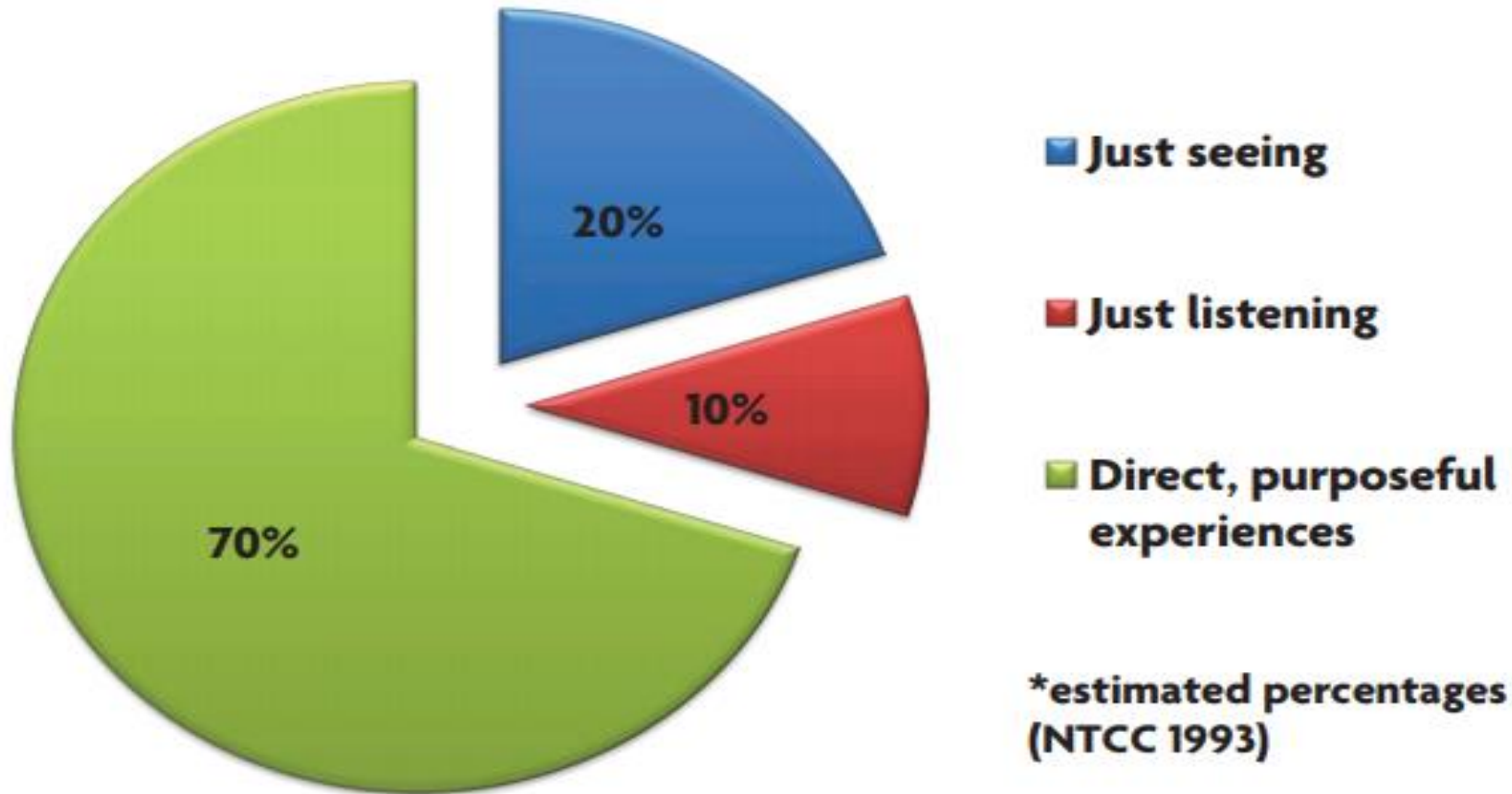
## Children

- Rely on others to decide what is important to be learned.
- Accept the information being presented at face value.
- Expect what they are learning to be useful in their long-term future
- Have little or no experience upon which to draw – are relatively “clean slates.”
- Little ability to serve as a knowledgeable resource to teacher or fellow classmates

## Adults

- Decide for themselves what is important to be learned
- Need to validate the information based on their beliefs and experience.
- Expect what they are learning to be immediately useful.
- Have much experience upon which to draw – may have fixed viewpoints.
- Significant ability to serve as a knowledgeable resource to trainer and fellow learners

# Percent of Adult Recall in the Learning Process



# Adult Learners

- Interactive
- Immediately Applicable
- Multi level Engagement
- Ability to Apply past and recently gain knowledge

# Certifications

## ACRP

### Association of Clinical Research Professionals

- 4 exam types – Clinical Research Associate, Clinical Research Coordinator, Principle Investigator, ACRP Certified Professional
- Computer Based testing (twice annually)
- Membership Fees: \$150 per year
- Certification Costs: \$435/\$460
- Length of Certification: 2 years
- Certification Maintenance: Continuing Education, Continuing Involvement, and Recert cost \$225/\$250/\$325

## SoCRA

### The Society of Clinical Research Associates

- 1 exam type – Clinical Research Professional
- Paper and Computer Based testing
- Membership Fees: \$75 per year
- Certification Costs: \$395 (additional \$115 for CBT)
- Length of Certification: 3 years
- Certification Maintenance: Continuing Education and Recert cost \$350 must complete learning module



# Johns Hopkins Training

- JH School of Nursing Professional Programs
  - Research Coordinator Training Course
  - First Friday Lectures
- My Learning
  - Training online and in person in a variety of topics
  - IRB training, Biohazard Training, DOT/IATA training
  - <https://lms14.learnshare.com/dashboard/dash.home.aspx?Z=303XUdNOjuqsElviRmjQiH2j1gxo%2fxRKWAlF%2fU%2b0Z0o%3d&LSMID=>
- Coursera
  - <https://www.coursera.org/programs/coursera-for-johns-hopkins-university-zfk78?authProvider=jhu>

# JH School of Nursing Professional Programs

- Research Coordinator Training Program (RCTP)
  - May 8-10 2019
  - Cost \$1900 (Professional Development Dollars)
  - <https://learn.nursing.jhu.edu/face-to-face/courses/research-coordinator/index.html>

# My Learning

- Required Training
- Any courses that have fees are covered by Professional Development
- History Log of all training online

# My Learning

Search

Search Results

Catalog

IRB

Mosby Clin. Skills

Performance Mgt.

Skillsoft

Sort Results: By Course Title, Ascending Order



(Coeus 2) Proposal Development Detail: Assembling a Proposal

Course Rating



Training Type

Computer Lab  
(Instructor Led -  
Hands on)

Time Provider

Learning Solutions  
3 hrs (Talent Management) -  
JHU

A Complete Guide to Clinical Research Billing Compliance

Course Rating



Training Type

Instructor Led 4 hours

Provider

Clinical Research Support  
Services (CRSS)

Account Reconciliation

Course Rating



Training Type

Computer Lab  
(Instructor Led -  
Hands on)

Time Provider

Learning Solutions  
3 hrs (Talent Management) -  
JHU

Administrative Management of Training Grants & Fellowships

Course Rating



Training Type

On-line

Time Provider

60 mins Learning Solutions (Talent  
Management) - JHU

Alone then Together: Building More Creative Meetings

Course Rating



Training Type

On Line

Time

n/a

Provider

SkillSoft Books24x7

Audio Lecture: Informed Consent: What Contributes to a Good Process

Course Rating



Training Type

On-line

Time

n/a

Provider

JHU Learning Solutions

# Coursera

- Online Course taught by Instructors for Universities and Educational Institutes Worldwide
- Free Course – Some Paid Certificate and Degree Programs
- Mobile Access

# Coursera

## Refine results

You searched for **Clinical Research**. 28 matches

### All Topics

☐ Business 2 ▾

☐ Computer Science 1 ▾

☐ Data Science 2 ▾

☐ Math and Logic 1 ▾

☐ Social Sciences 3 ▾

Languages (14)



### Patient Safety

Johns Hopkins University

7 COURSES



### Foundations of Global Health

Johns Hopkins University

6 COURSES



### Executive Data Science

Johns Hopkins University

5 COURSES



### Genomic Data Science

Johns Hopkins University

8 COURSES

# ICTR Resources



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Q SEARCH

HOME

NEWS & EVENTS

SERVICE REQUESTS

PROGRAMS & RESOURCES

COLLABORATIONS

CTSA PARTNERSHIPS

FUNDING OPPORTUNITIES

TRAINING & EDUCATION

COMMUNITY INVOLVEMENT

TRIALS @ HOPKINS

ABOUT US



MYPATH STORY BOOTH PROJECT

[https://ictr.johnshopkins.edu/study\\_team/training-education/](https://ictr.johnshopkins.edu/study_team/training-education/)

# The Science of Clinical Investigations (SOCI)

- <https://www.jhsph.edu/academics/graduate-training-programs-in-clinical-investigation/advanced-training/online-soci-training-program.html>
- 390.678.81 Quality Improvement and Knowledge Translation (First Term)
- 390.673.81 Ethical and Regulatory Issues in Clinical Research (Second Term)
- 390.676.81 Design of Clinical Studies (Third Term)
- 390.672.81 Quantitative Analysis of Clinical Data (Fourth Term)



# Tuition Remission

<http://benefits.jhu.edu/tuition/remission.cfm>

- You are eligible for tuition remission once you have completed 120 days of full-time employment as long as you are JHU faculty, staff or a retiree.
- Visiting faculty and staff, residents, interns and post-doctoral fellows are not eligible for tuition remission

# Tuition Remission

<http://benefits.jhu.edu/tuition/remission.cfm>

- Part-time credit and non-credit courses offered through the continuing education unit of one of JHU's academic divisions are covered under this plan.
- Outside courses, conferences, and seminars may also be covered if required for the employee to maintain a job-required professional certificate or license regulated by the State Licensing Board.

# Tuition Remission

<http://benefits.jhu.edu/tuition/remission.cfm>

- There is a \$5,250 annual family limit on tuition remission for faculty, staff, retirees
- You are responsible for any spending that exceeds the limits, and for tuition costs for courses not completed (i.e., withdrawn or dropped).
- Faculty, staff, and retirees are eligible for 100% remission for credit courses, and 25% remission for private credit instruction at Peabody.

# Tuition Remission – Professional Development

- <http://benefits.jhu.edu/tuition/remission.cfm>

- There is no annual dollar limit or reduction of annual limits for non-credit professional development or personal enrichment courses.
- You receive 100% remission if your department certifies the course is valuable for your professional development and your department is willing to pay if you do not attend or cancel from the course with at least one week's notice.

# Upcoming Events

**Tuesday, January 22, 1:00 p.m.-2:30 p.m.**

*2024 East Monument Street, 1-500Q*

**Readying the R: Gail L. Daumit, MD, MHS, FACP,** Samsung Professor of Medicine, General Internal Medicine, Psychiatry and Behavioral Sciences, Epidemiology, Health Policy and Management and Mental Health; Research Director, Division of General Internal Medicine; Co-Chair, Institutional Review Board X;  
**Elise Weerts, PhD,** Professor, Department of Psychiatry and Behavioral Sciences

[Click here to register](#)