The Importance of Continued Research Training & Available Resources at Johns Hopkins
Regulatory Changes in Clinical Research

• 2016

• 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

https://www.clinicaltrialcompetency.org/
Competency Domains for the Clinical Research Professional

1. Ethical and participant safety considerations
2. Investigational products development and regulation
3. Clinical study operations (GCPs)
4. Study and site management
5. Data management and informatics
6. Leadership and professionalism
7. Communication and teamwork
8. Scientific concepts and research design
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.

[https://www.pacer.org/publications/fasttraining/Other/teachingadults-whattrainersneedtoknow.pdf](https://www.pacer.org/publications/fasttraining/Other/teachingadults-whattrainersneedtoknow.pdf)
Percent of Adult Recall in the Learning Process

- 70%: Direct, purposeful experiences
- 20%: Just seeing
- 10%: Just listening

*estimated percentages (NTCC 1993)
Adult Learners

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

<table>
<thead>
<tr>
<th>ACRP</th>
<th>SoCRA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Association of Clinical Research Professionals</strong></td>
<td><strong>The Society of Clinical Research Associates</strong></td>
</tr>
<tr>
<td>• 4 exam types – Clinical Research Associate, Clinical Research</td>
<td>• 1 exam type – Clinical Research Professional</td>
</tr>
<tr>
<td>Coordinator, Principle Investigator, ACRP Certified Professional</td>
<td></td>
</tr>
<tr>
<td>• Computer Based testing (twice annually)</td>
<td>• Paper and Computer Based testing</td>
</tr>
<tr>
<td>• Membership Fees: $150 per year</td>
<td>• Membership Fees: $75 per year</td>
</tr>
<tr>
<td>• Certification Costs: $435/$460</td>
<td>• Certification Costs:$395 (additional $115 for CBT)</td>
</tr>
<tr>
<td>• Length of Certification: 2 years</td>
<td>• Length of Certification: 3 years</td>
</tr>
<tr>
<td>• Certification Maintenance: Continuing Education, Continuing</td>
<td>• Certification Maintenance: Continuing</td>
</tr>
<tr>
<td>Involvement, and Recert cost $225/$250/$325</td>
<td>Education and Recert cost</td>
</tr>
<tr>
<td></td>
<td>$350 must complete learning module</td>
</tr>
</tbody>
</table>
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=303XUdNOjuqsElviRmjQiH2j1gx0%2fxRKWAIF%2fU%2b0Z0o%3d&LSMID=

• Coursera
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
<table>
<thead>
<tr>
<th>Course Title</th>
<th>Training Type</th>
<th>Time</th>
<th>Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Coeus 2) Proposal Development Detail: Assembling a Proposal</td>
<td>Computer Lab (Instructor Led - Hands on)</td>
<td>3 hrs</td>
<td>Learning Solutions (Talent Management) - JHU</td>
</tr>
<tr>
<td>Account Reconciliation</td>
<td>Computer Lab (Instructor Led - Hands on)</td>
<td>3 hrs</td>
<td>Learning Solutions (Talent Management) - JHU</td>
</tr>
<tr>
<td>Administrative Management of Training Grants &amp; Fellowships</td>
<td>On-line</td>
<td>60 mins</td>
<td>Learning Solutions (Talent Management) - JHU</td>
</tr>
<tr>
<td>Alone then Together: Building More Creative Meetings</td>
<td>On Line</td>
<td>n/a</td>
<td>Skillsoft Books24x7</td>
</tr>
<tr>
<td>Audio Lecture: Informed Consent: What Contributes to a Good Process</td>
<td></td>
<td></td>
<td>University of Maryland - College Park</td>
</tr>
</tbody>
</table>

**Sort Results:** By Course Title, Ascending Order
• Online Course taught by Instructors for Universities and Educational Institutes Worldwide
• Free Course – Some Paid Certificate and Degree Programs
• Mobile Access
You searched for **Clinical Research**. 28 matches

- **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
The Science of Clinical Investigations (SOCl)

- [https://www.jhsph.edu/academics/graduate-training-programs-in-clinical-investigation/advanced-training/online-soci-training-program.html](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

- 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.

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