



**MULTI-REGIONAL
CLINICAL TRIALS**

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

Joint Task Force for Clinical Trial Competency (JTF)

Improving the efficacy, quality and safety of clinical trials globally

Barbara E. Bierer, MD
Professor of Medicine, Harvard
Medical School
Faculty Director, MRCT Center

Stephen A. Sonstein, PhD
Senior Advisor, MRCT Center

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UNDERSTAND ENGAGE ACT



The **MRCT Center** is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.

Affiliated with



BRIGHAM AND
WOMEN'S HOSPITAL



HARVARD
UNIVERSITY



Our Vision

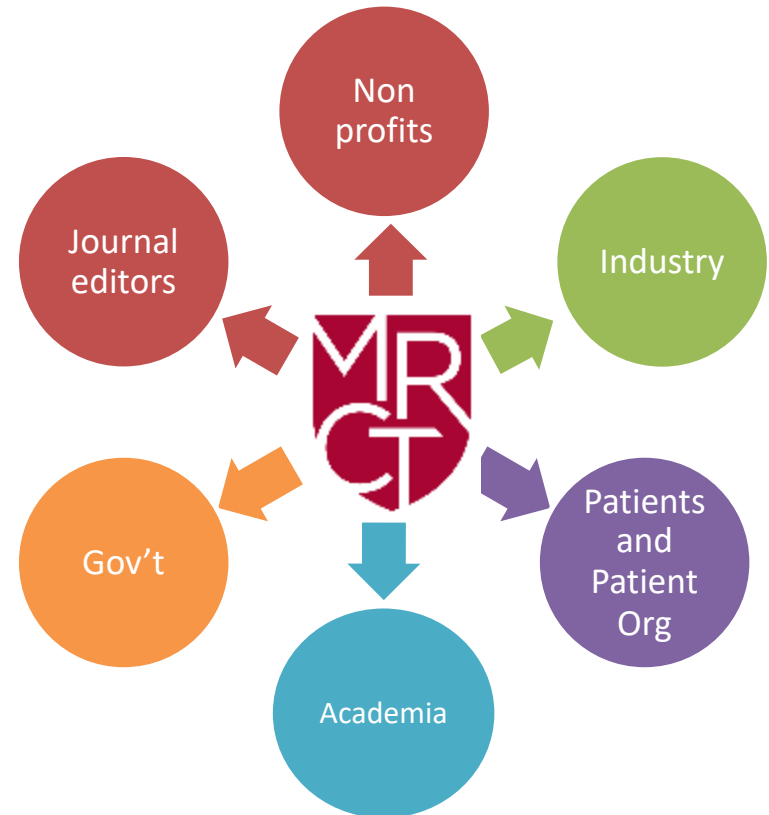
Improve the integrity, safety, and rigor of global clinical trials.



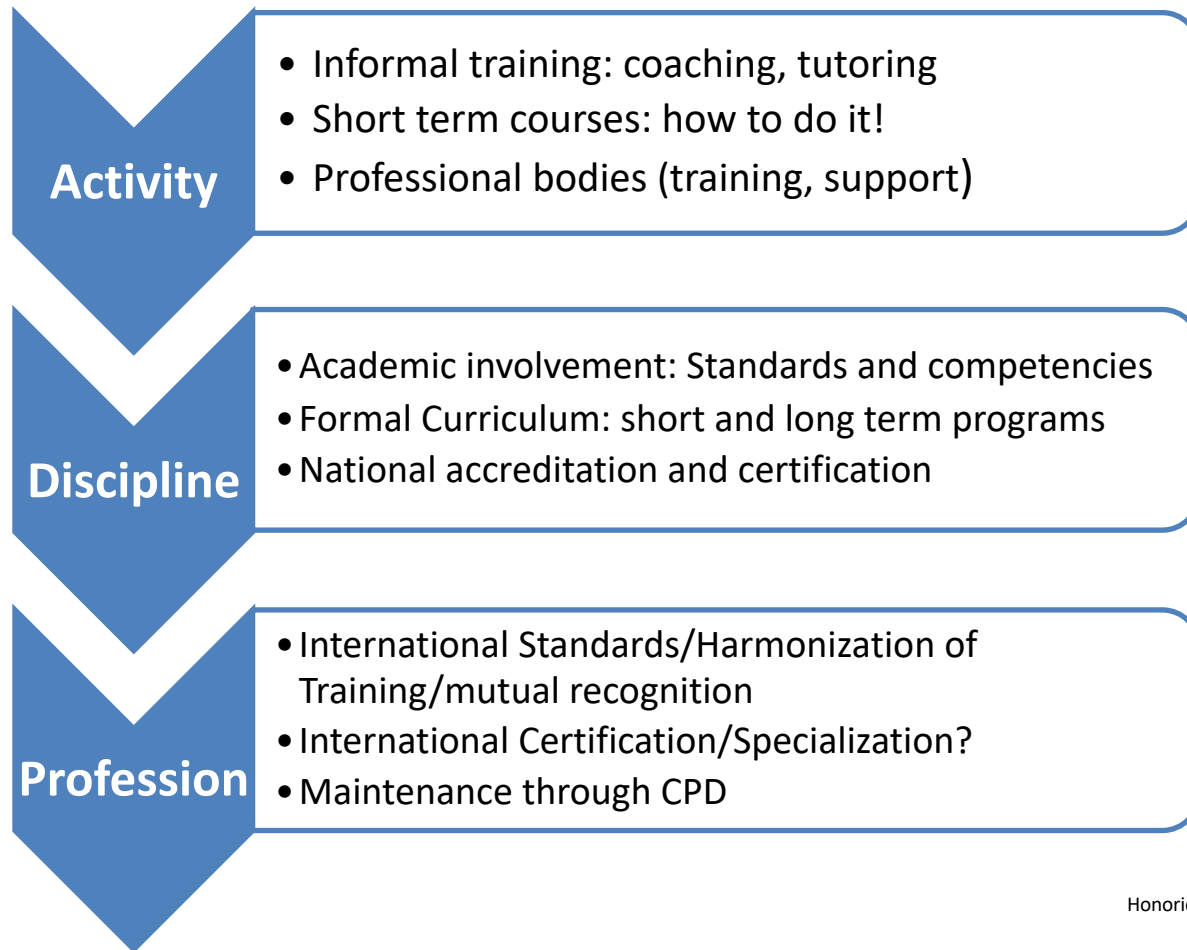
- Academic credibility
- Trusted collaborator
- Independent convener

Our Community

We engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.



Evolution of Education and Training in Clinical Research



Honorio Silva MD, 2010

Core Competencies and Education

- Competencies consist of a description of the essential skills, knowledge, attitudes, and behaviors required for effective performance of a real-world task or activity. These activities may be related to any domain of life, though have typically been linked to the field of work and to social survival in a new environment.¹
- Outcomes-based/competency-based education improves performance, enhances communication, and provides an impetus for faculty development, curricular reform, and leadership in educational innovation.²
- Competency-based education has begun to redefine accreditation and certification across the health professions.³

¹Mrowicki, L., (1986)., Project Work English Competency Based Curriculum. Portland, OR: Northwest Educational Cooperative, p. 144.

² Committee on the Health Professions Education Summit. *Health Professions Education: A Bridge to Quality*. Washington, DC: Institute of Medicine; 2005

³ Shortell SM, Weist EM, Mah-Sere KS, Foster A. Implementing the Institute of Medicine's recommended curriculum content in schools of public health: a baseline assessment. *Am J Public Health*. 2004;94:10, 1671–1674

Joint Task Force (JTF) for clinical trial competency: Defining professional competence throughout the clinical research enterprise

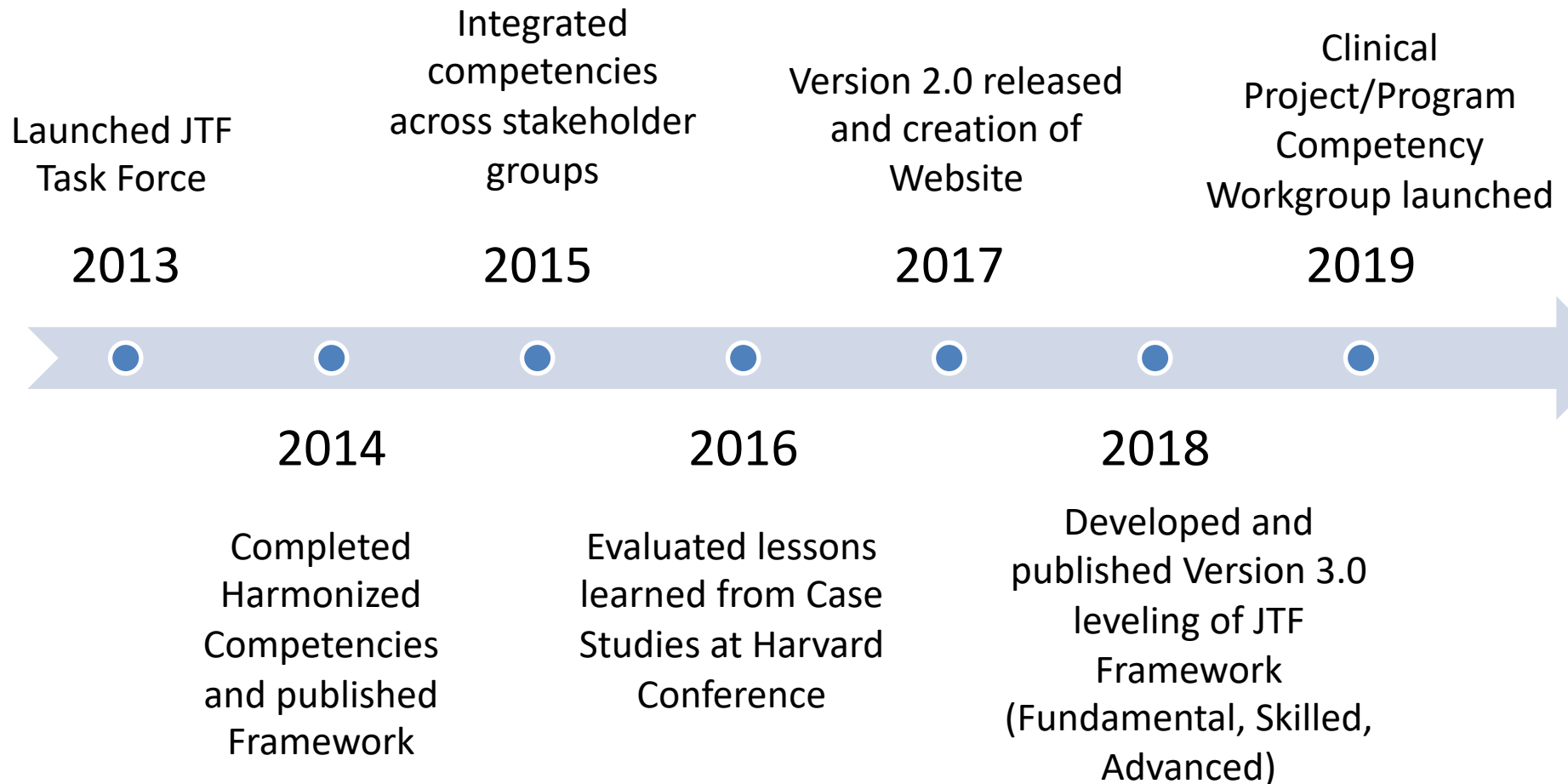
- First meeting 2013 at Harvard University
- Multiple representatives from industry, academy, nonprofit organizations
- International collaboration



JTF Vision

- **To develop a universally applicable, globally relevant harmonized competency framework for clinical research professionals**
- To align competency-based efforts (e.g., education, training, and workforce development) across the clinical research enterprise
- To identify knowledge, skills, and attitudes that are essential for the successful, ethical, and safe conduct of clinical trials
- To build a framework that can adapt to meet the needs of clinical researchers as the discipline evolves and advances
- To facilitate the success and development of current and aspiring clinical research professionals
- To align stakeholders across the clinical research enterprise—including academia, industry, government, non-profits and professional societies

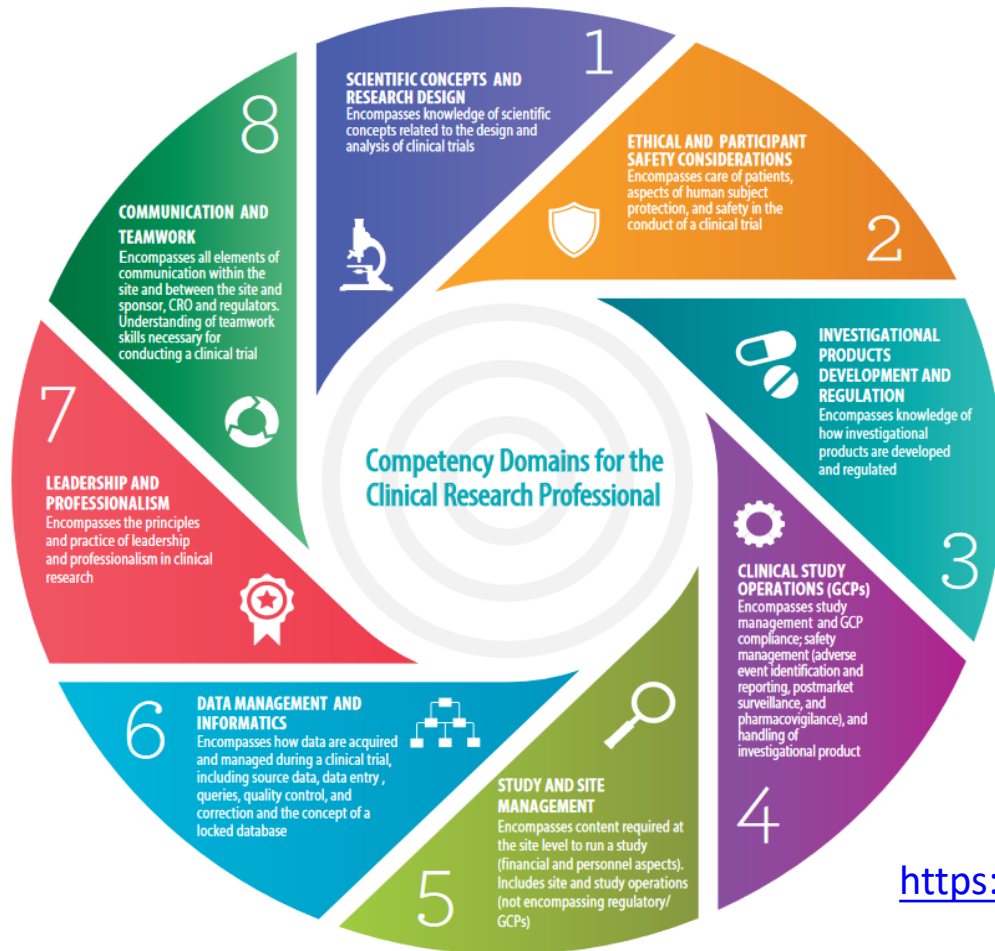
JTF Timeline of Clinical Trial Competencies



Links to JTF Resources

- JTF Core Competency Framework for the Clinical Research Professiona'
- Main Webpage
 - <https://mrctcenter.org/clinical-trial-competency/>
 - <https://mrctcenter.org/clinical-trial-competency/framework/domains/>
- Download JTF Competency Framework (version 3.0)
 - <https://mrctcenter.org/wp-content/uploads/2018/12/2019-03-13-Leveled-Core-Competencies-Version-3.0-Updated-URL.pdf>
- Download JTF Spanish Version
 - <https://mrctcenter.org/clinical-trial-competency/framework/translations/spanish-2/>

JTF Framework: Competency Domains for the Clinical Research Professional



Sonstein, S.A., Seltzer, J., Li, R., Jones, C.T., Silva, H., Daemen, E. (2014, June). **Moving from compliance to competency: A harmonized core competency framework for the clinical research professional.**

- *Clinical Researcher*. 28(3); 17-23
- *Applied Clinical Trials*. May 28, 2014
- *Journal of Clinical Research Best Practices*,10(6); 1-12.
- *CenterWatch Whitepapers*, June, 2014.

<https://mrctcenter.org/clinical-trial-competency/>

Use of Competencies

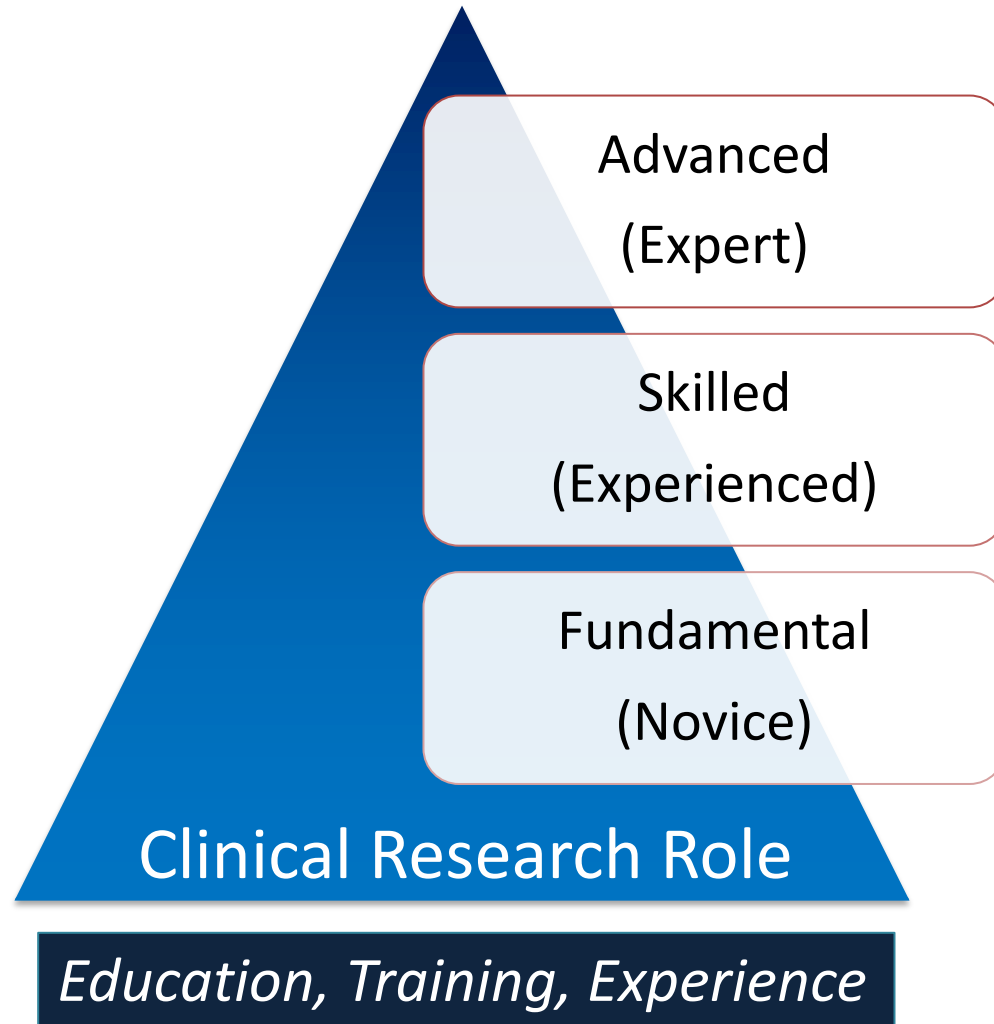
- Standardized role descriptions
- Competency-based training/education
- Level of competency vs level of job
 - Promotion and professional development
- Self-assessment & competence
 - Recognize personal training needs
 - Personal portfolio of competencies
- Competence & career development
 - Academic program accreditation
- Continuous process (competence not static, jobs change, gaps appear); lifelong learning

Utilization of JTF Framework: Examples

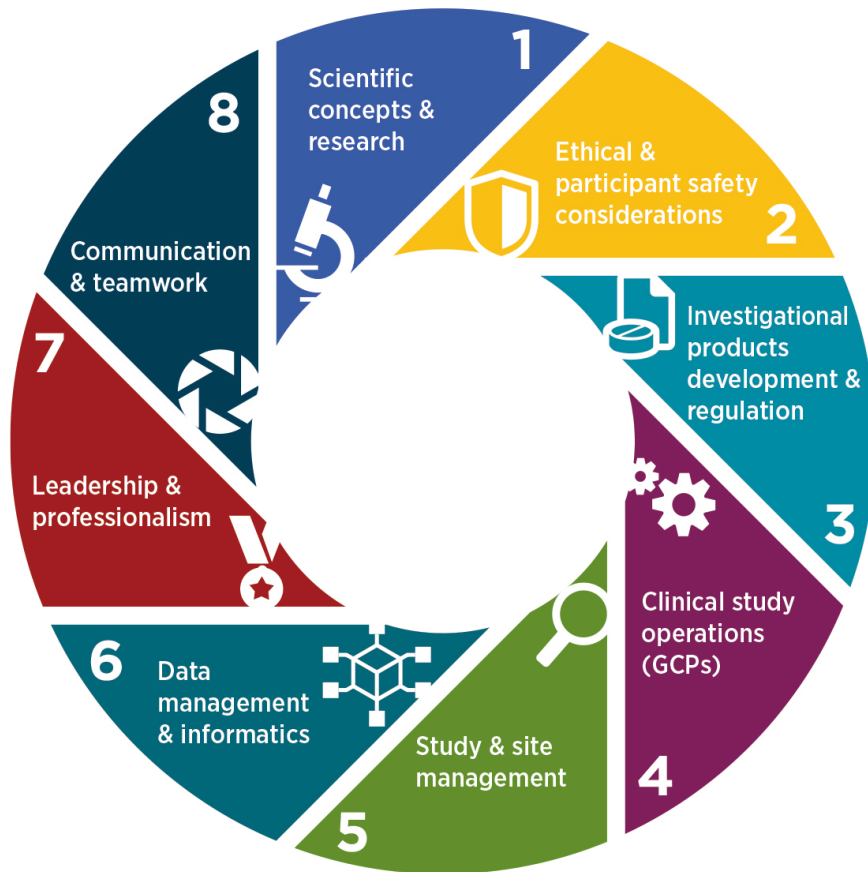
- **ACRP** – organized annual meeting tracks and professional certification examination based on JTF Framework
- **Duke University** – restructured research job classifications based on competencies. Went from over hundred to fewer than 20. Restructured promotion criteria
- **Takeda Pharmaceuticals** – reorganized internal training programs based on competency framework
- **CTSA** adopted core competency framework as basis for clinical investigator training program
- **CAAHEP** sponsored accreditation of academic programs in clinical research. Standards based on JTF framework
- **The UK National Institute for Health Research (NIHR) Clinical Research Network (CRN)** has used the JTF Framework in a clinical research workforce development initiative called the Integrated Workforce Framework (IWF).

[Proceedings available on MRCT website](#)

Professional Growth: Fundamental to Expert



Leveling of the JTF Core Competency Framework (2018)



SKILL LEVELS

- **Fundamental level:**
can perform with coaching/explain
- **Skilled level:**
can perform independently/demonstrate
- **Advanced level:**
can teach/develop

JTF Framework 3.0 - leveling (or tiers) of competencies

Domain 2 – Ethical and Participant Safety Considerations

2.1 Differentiate between standard of care and clinical study activities

Fundamental Level

A1. Explain that a clinical study is unconfirmed research and not accepted standard of care

Example: Explains to a study participant that procedures that are part of the protocol are not necessarily standard of care.

Skilled Level

B1. Demonstrate the importance of conducting clinical trial activities as per the protocol

Example: Explains to clinical staff the timing of a research blood draw versus standard blood draw timing for the shift.

Advanced

C1. Develop a protocol that appropriately includes distinct research activities and standard of care

Example: Appropriately distinguishes between activities that should be billed to insurance versus incorporated into sponsored cost.

Future JTF Activities

- **Clinical Project Management competencies**
- **Personal competency portfolios**
 - Individuals can apply for employment or promotion based on documented competencies instead of “length of time of employment”
- **Development of Metrics to show impact of integration of competency framework in to the clinical research enterprise**
- **Global integration of Core Competency Framework**
 - Are there cultural or financial issues which impact the JTF Framework in certain regions?

Questions, Comments, Suggestions

Thank you

Barbara E. Bierer, MD

bbierer@bwh.harvard.edu

+1-617-827-7413

