ACRP

FOR LEARNING FOR LISTENING FOR LIFE

Competency Based Career Progression

Beth Harper, BSOT, MBA
ACRP, Workforce Innovation Officer

CRP Taskforce Webinar-16-January, 2019

© Association of Clinical Research Professionals acrpnet.org

Please Raise Your Hand (Virtually…)

If you think you are a COMPETENT Clinical Research Professional!

© Association of Clinical Research Professionals ▯ acrpnet.org

ACRP

How Would I (or anyone!) Know?

© Association of Clinical Research Professionals | acrpnet.org

ACRP

Learning Objectives

At the end of this session you should be able to:

- Identify the elements that contribute to competency
- List the JTF (Joint Task Force) Harmonized Competencies for Clinical Research Professionals and discuss how they can be used for career / employee development
- Discuss the current initiatives and resources available through ACRP to promote a more competent workforce
- Describe ways that you can apply competency based approaches to your own career progression as well as within your organization

© Association of Clinical Research Professionals

ACRP

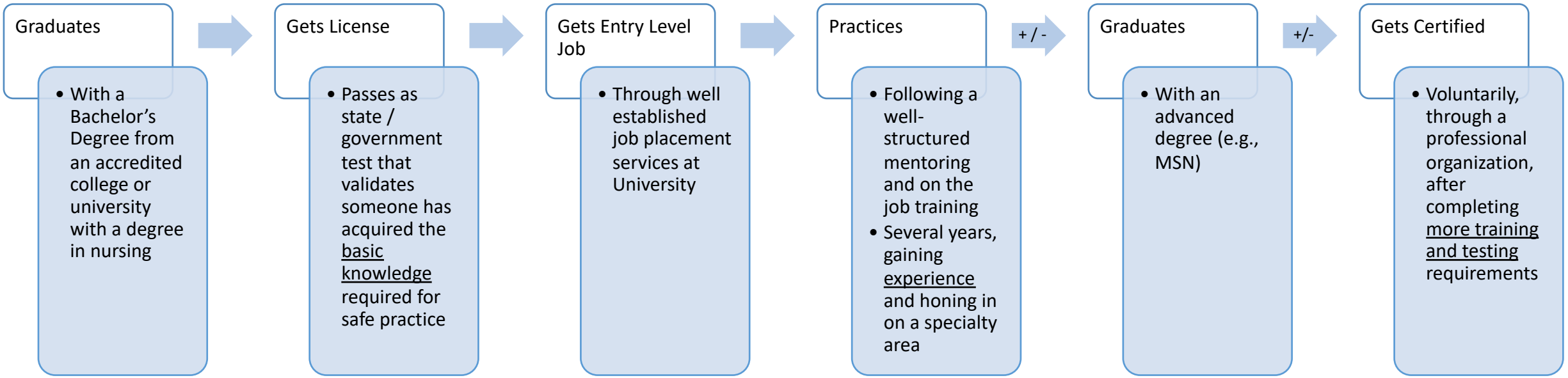
Competency Based Workforce Development

Who Cares?

© Association of Clinical Research Professionals | acrpnet.org

ACRP

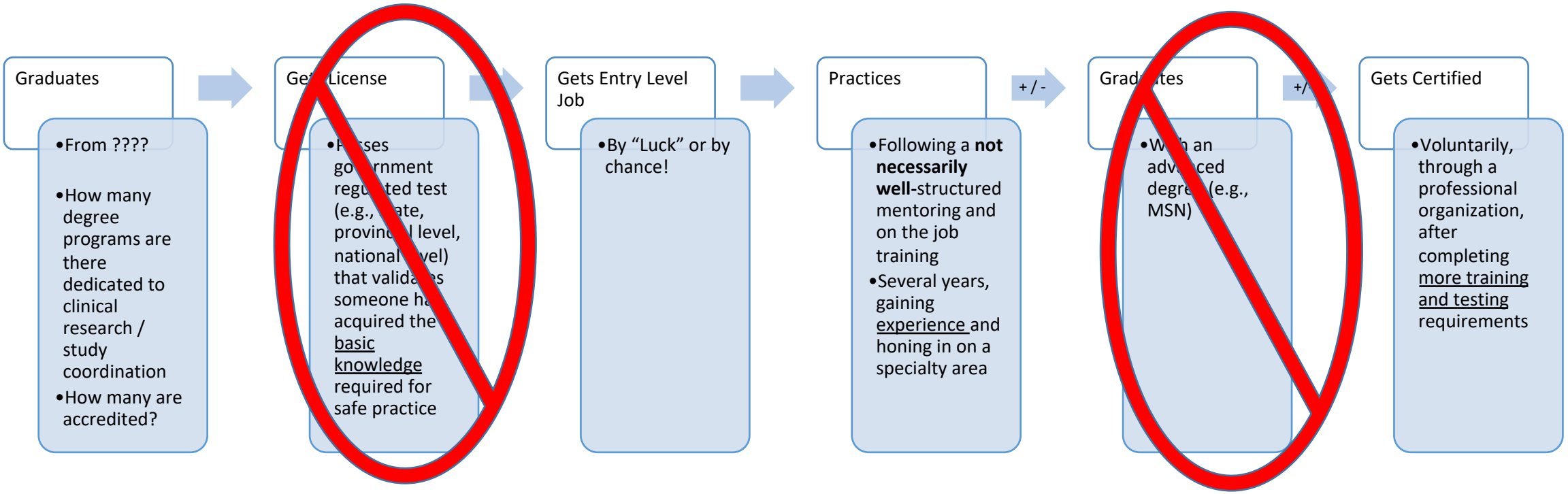
Take Nursing for Example



© Association of Clinical Research Professionals ⍰ acrpnet.org

ACRP

Take a Clinical Research Coordinator for Example



© Association of Clinical Research Professionals ⍰ acrpnet.org

ACRP

What's Missing?

- Per FDA guidelines Sponsors shall select investigators / monitors "qualified by training and experience"

- Per health Canada guidelines, Qualified Investigators (QI) must be "member in good standing of a professional medical or dental association"

- Per ICH GCP "Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)."

© Association of Clinical Research Professionals

ACRP

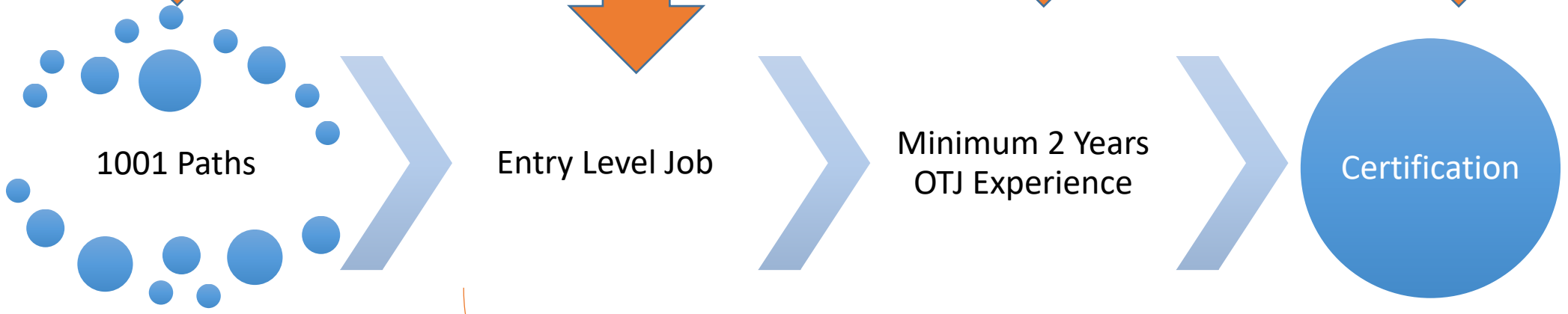
"Expected Standards" in Clinical Research Don't Exist

There are no "Standards" for getting into the field

There are no standard job descriptions, let alone "Standards" for evaluating entry level competencies

Tenure doesn't equate to competency!

Not all clinical research professionals get Certified



To Get into Clinical Research!

There are no mandatory regulations, standards or licensure requirements for specific job roles within clinical research, nor accreditation requirements (yet) for academic programs, nor standards for internal or external training programs

© Association of Clinical Research Professionals | acrpnet.org

ACRP

Would You Go To or Use Any of the Following If They Weren't Licensed?

- Building Contractors
- Cosmetologists
- Relators
- Teachers
- Doctors, Nurses, Therapists
- Electricians
- Lawyers
- Etc.
- Accountants
- Veterinarians
- Architects

© Association of Clinical Research Professionals | acrpnet.org

ACRP

Many Professions Require Basic Licensure

Purpose

- Intended to ensure the public that a person is competent to practice in that profession. (Or at least validates someone has acquired the basic knowledge required for safe practice)

When is It Needed?

- Generally licenses are needed to regulate an activity whose incompetent execution would be a threat to the public

Expectations

- To obtain a license one must demonstrate that they meet state or other standards for that career.

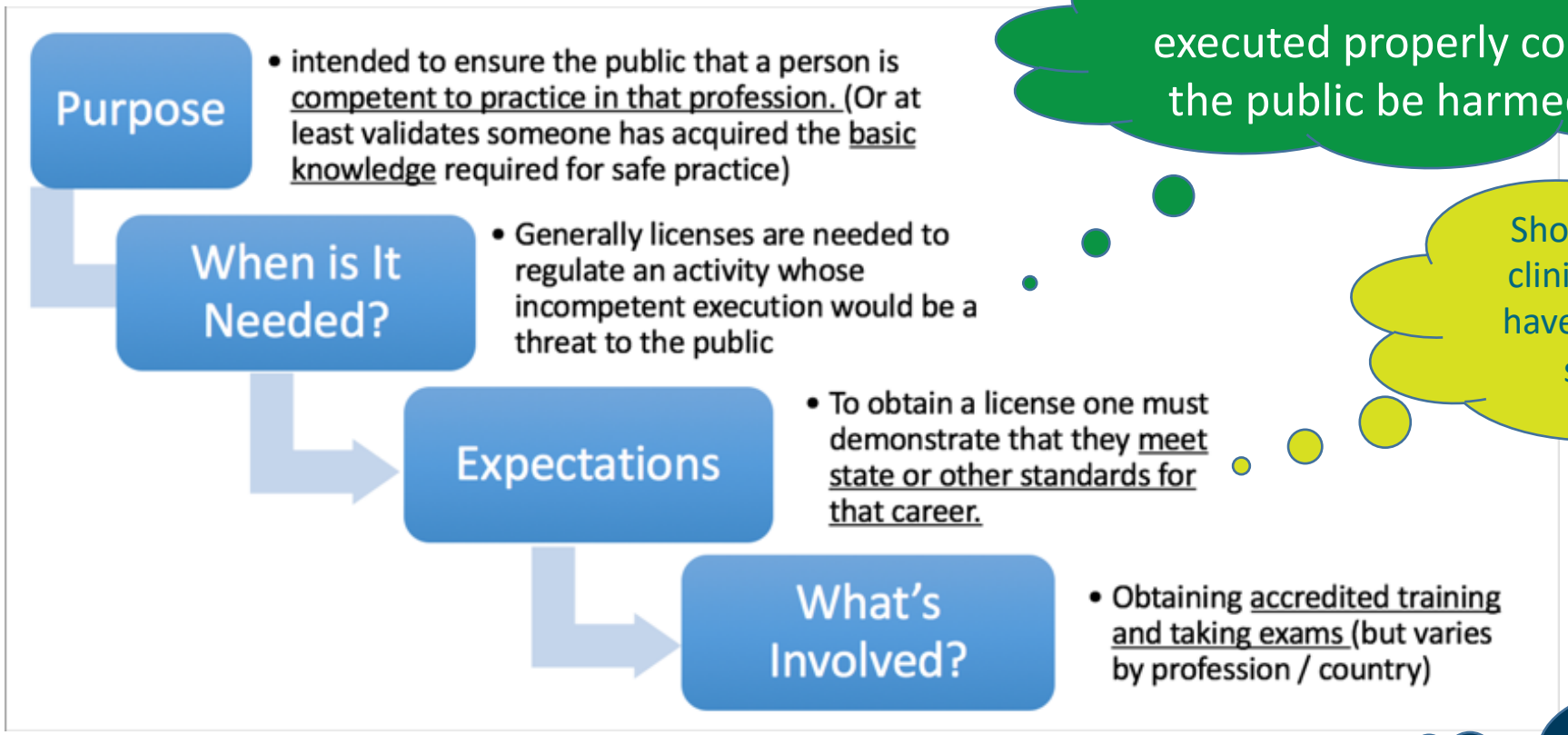
What's Involved?

- Obtaining accredited training and taking exams (but varies by profession / country)

© Association of Clinical Research Professionals | acrpnet.org

ACRP

Should the Licensure Concepts Apply to Clinical Research?



If clinical research isn't executed properly could the public be harmed?

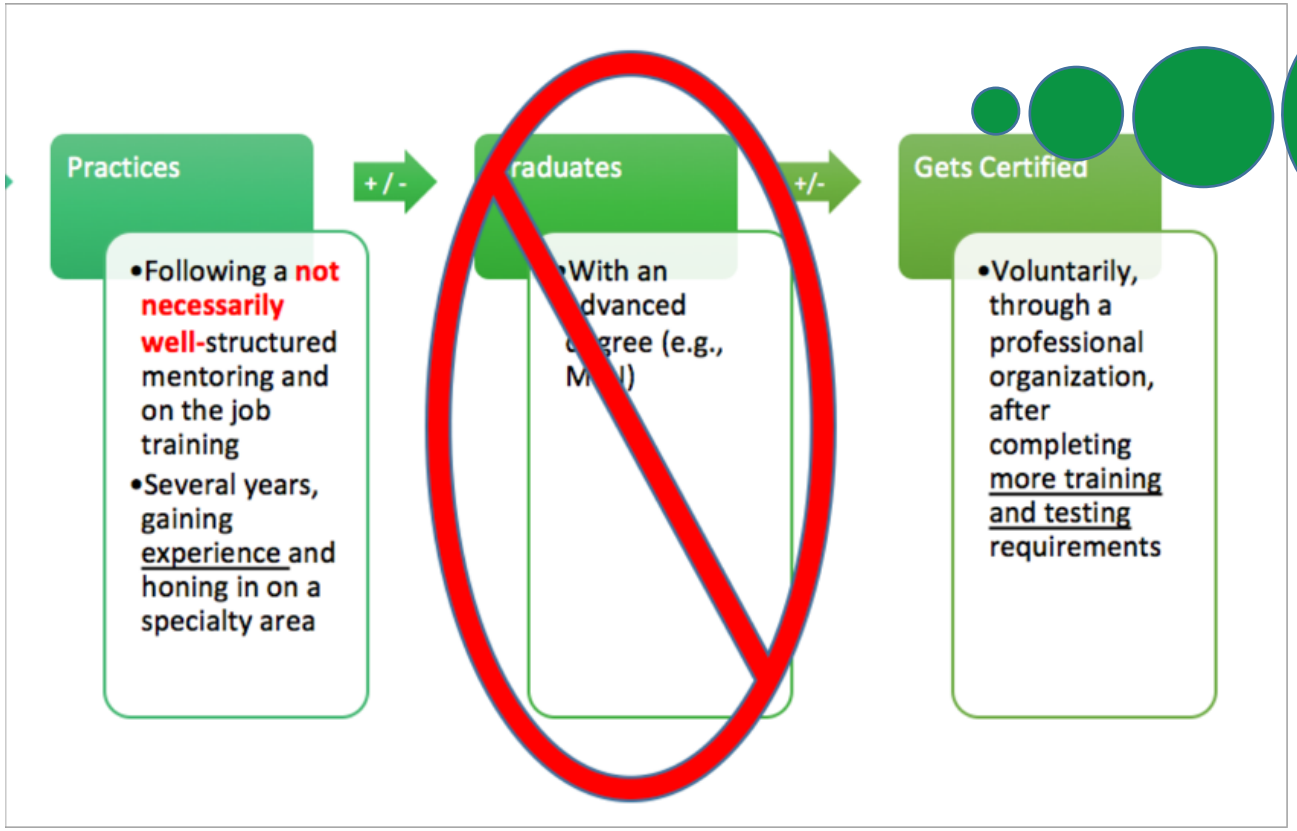
Should the public expect that clinical research professionals have demonstrated they meet some basic standards?

Should any one working in clinical research take a basic knowledge exam (e.g., Entry Level Assessment) if not a formal, state-mandated licensure exam?

How can we ensure that we monitor ourselves to enhance quality before the government steps in and DOES require a license?

ACRP

Certification



While certification is voluntary for career advancement, should we require advanced degrees or some type of formal education requirements in order to be certified (i.e., not just minimum of 2 years of experience?

© Association of Clinical Research Professionals | acrpnet.org

ACRP

Our Dilemma

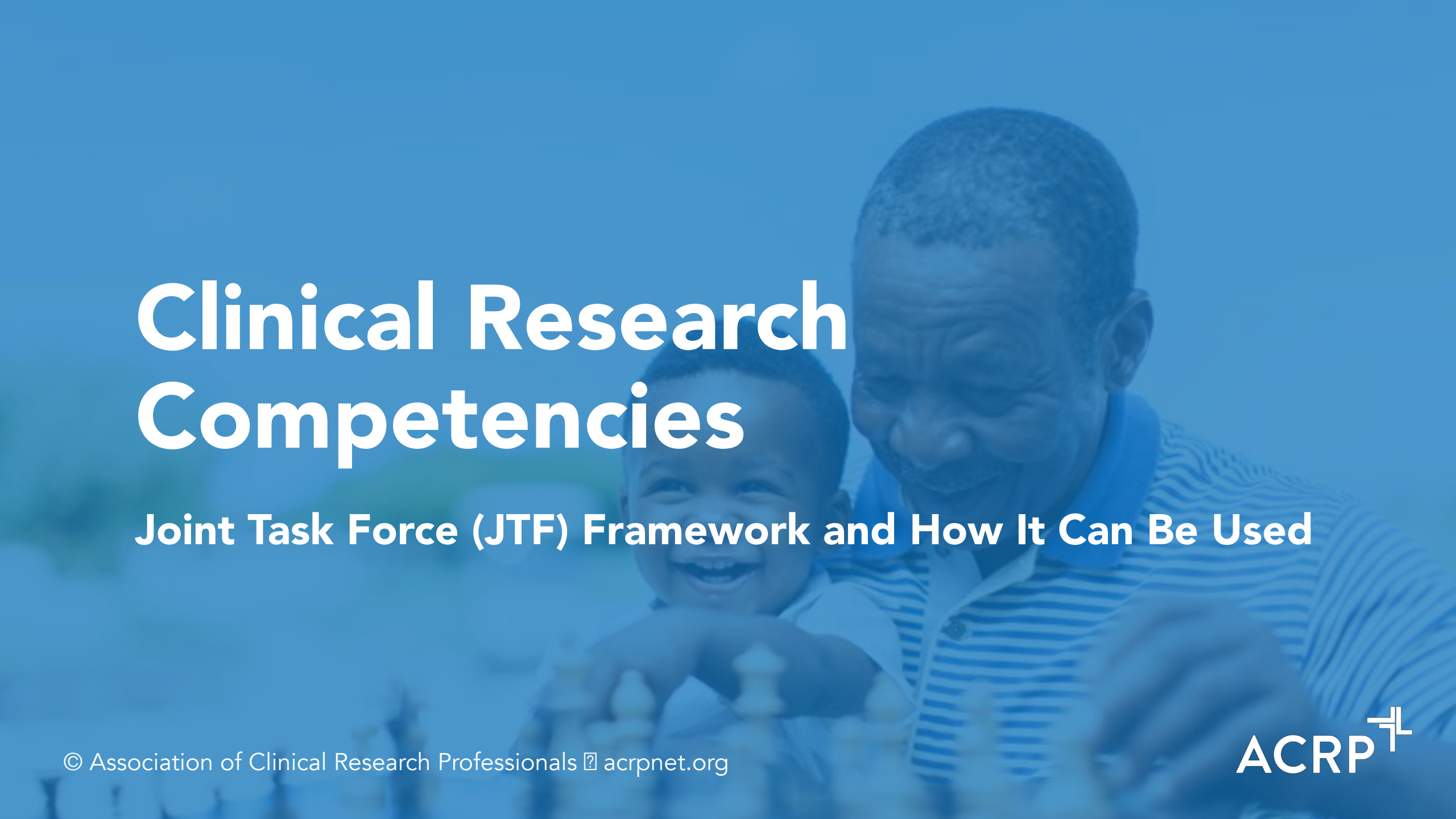
If I'm NOT Certified, Does This Mean That I am NOT Competent?

If I AM Certified, Does This Mean That I AM Competent?

How Would Anyone (The public? My employer?) Actually Know if I AM Competent?

© Association of Clinical Research Professionals | acrpnet.org

ACRP



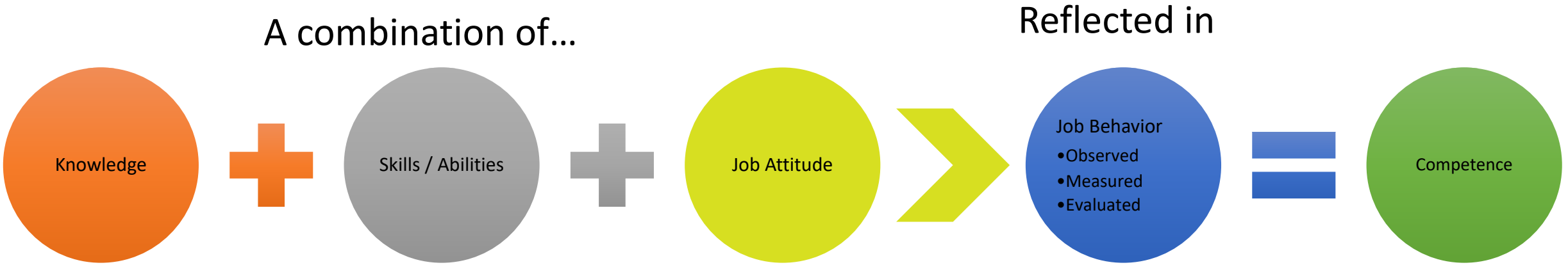
Clinical Research Competencies

Joint Task Force (JTF) Framework and How It Can Be Used

© Association of Clinical Research Professionals

ACRP

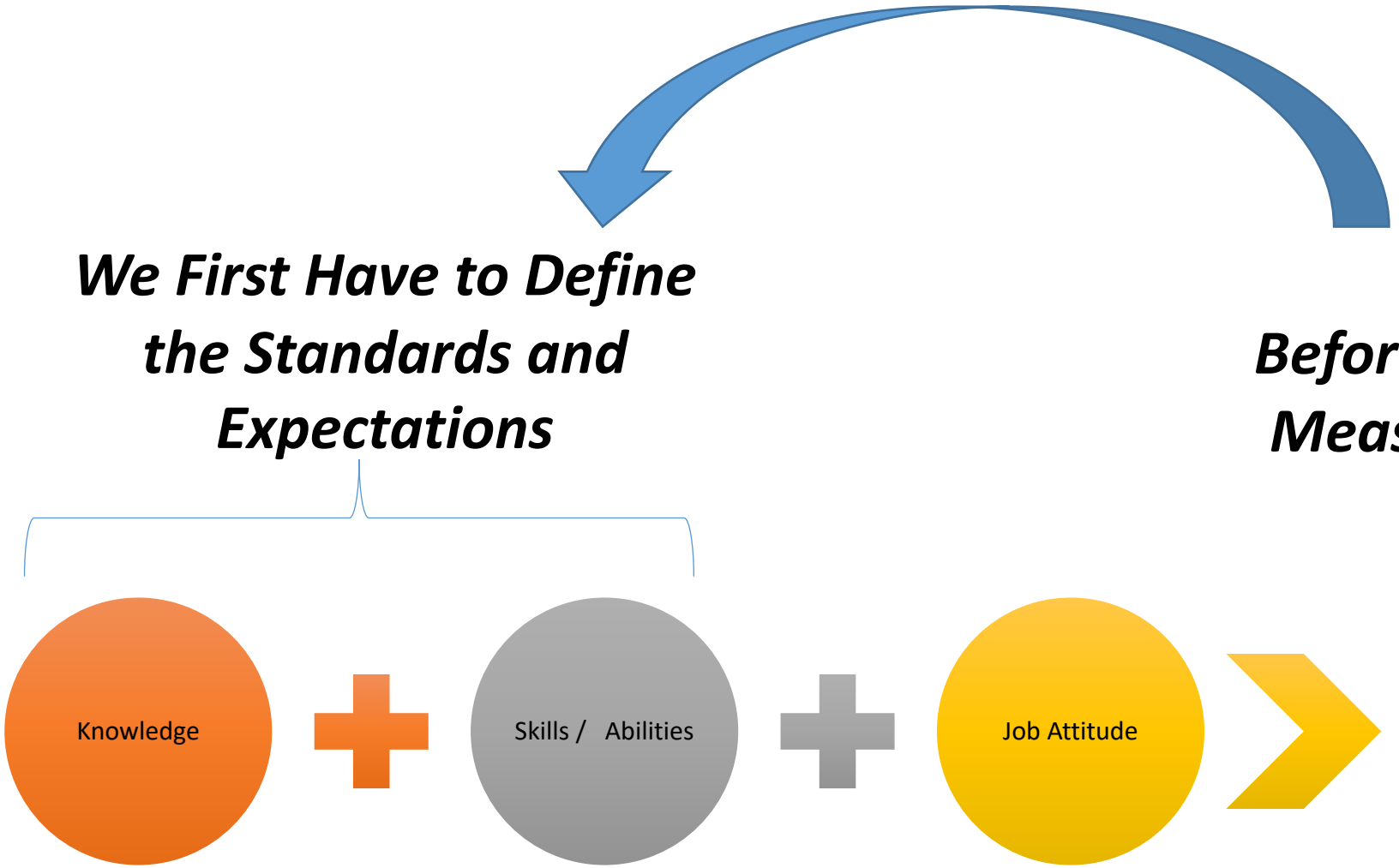
What Is Competence?



Source: Competency based HR Management. Retrieved from: https://www.slideshare.net/ZainiIthnin1/competency-based-hr-management-18080989

© Association of Clinical Research Professionals | acrpnet.org

ACRP



© Association of Clinical Research Professionals | acrpnet.org

ACRP

Standards for Clinical Research Professionals

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

https://www.clinicaltrialcompetency.org/

The Joint Task Force for Clinical Trial Competency has identified the skills required for safe, ethical, and high-quality clinical research. We are committed to providing researchers worldwide with guidance and tools to ensure the professional competency of all members of the research team.

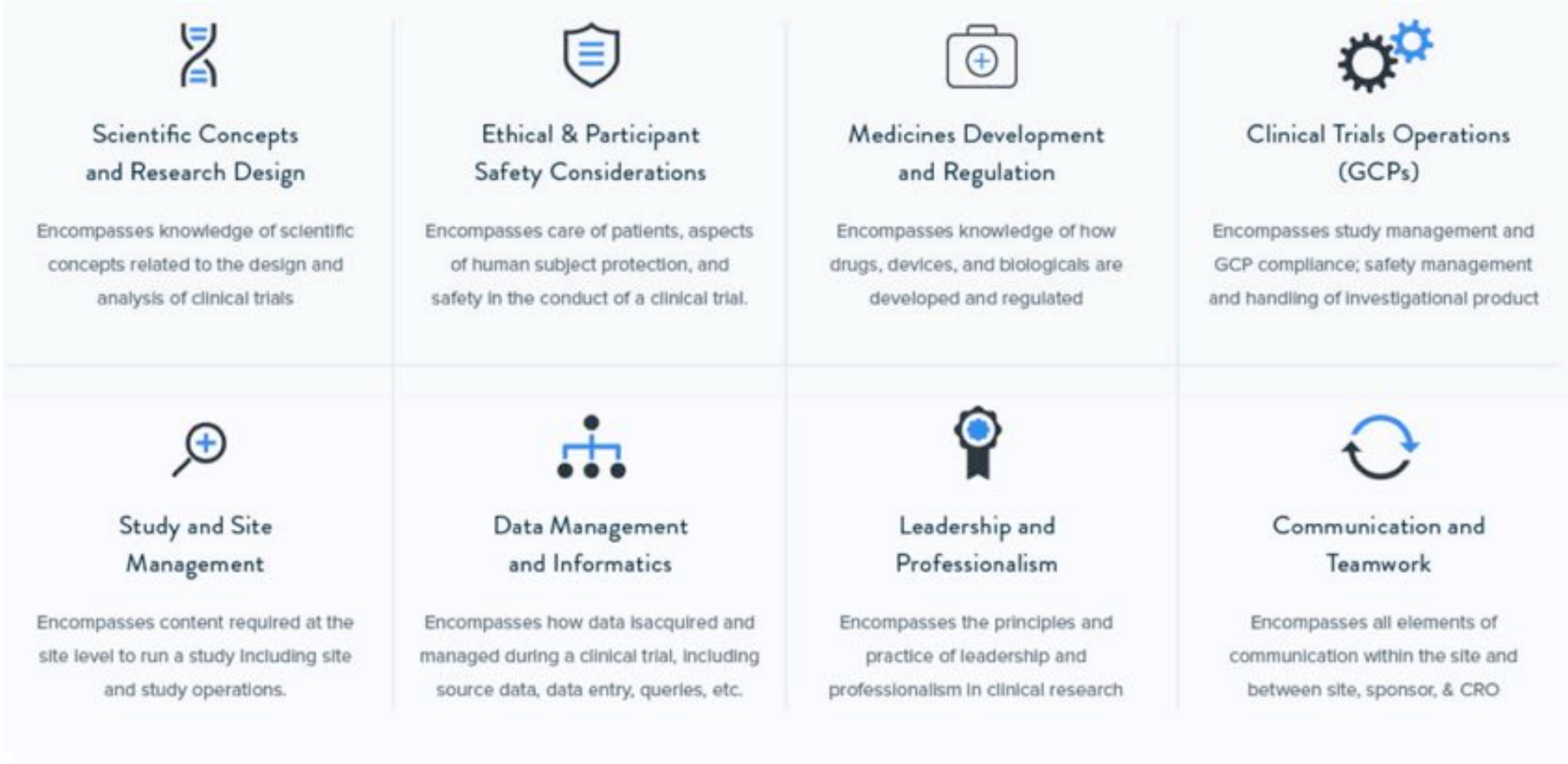
Core Competency Framework Version 2.0

The revised Core Competency Framework Version 2.0 was released On September 1, 2017.

© Association of Clinical Research Professionals

ACRP

Joint Task Force (JTF) Competency Domains



© Association of Clinical Research Professionals ⍰ acrpnet.org

ACRP

Competency Statements

Each of the 8 domains has specific competency statements. For example:

	Harmonized Core Competency Framework for the Clinical Research Professional
1	**Scientific Concepts and Research Design:** Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials
1.1	Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions
1.2	Identify scientific questions that are potentially testable clinical research hypotheses
1.3	Identify the elements and explain the principles and processes of designing a clinical study
1.4	Critically analyze clinical study results

Current Work of the JTF: Leveling the Competency Statements

Fundamental Level	Skilled Level	Advanced Level
Can perform the task and/or exhibit the knowledge at an essential or foundational level. May require some coaching or supervision.	Can perform task or skill independently, consistently, accurately, and has a moderate level of expertise. Efficient and high quality work. Able to independently navigate resources and uses tools well.	Demonstrates advanced skills and knowledge and the ability to teach, coach, or supervise others. Consistently applies critical thinking and problem solving.

Hot off the presses!
Sonstein, S. et al. Leveling the Joint Task Force Competencies for Clinical Research Professionals. Oct. 18, 2018. Therapeutic Innovation and Regulatory Science

A strategic decision was made to keep these generic and non role-based; thereby enabling other organizations such as ACRP to create role-based levels.

© Association of Clinical Research Professionals

ACRP

Harmonized Competencies Can Be Applied In Many Areas:

© Association of Clinical Research Professionals | acrpnet.org

ACRP

Competency-Based Hiring

© Association of Clinical Research Professionals | acrpnet.org

ACRP

Competency-Based Hiring Practices Should Result in Better Hires!

- Competencies are more likely than traditional hiring methods to determine on-the-job success.
- Clearly defined competency-based selection process can aid in recruiting, demonstrate fairness, encourage diversity, simplify the process of filling new openings and reduce turnover

There is a great resource on competency-based hiring that you may wish to review: https://www.shrm.org/hr-today/news/hr-magazine/pages/0315-competencies-hiring.aspx

© Association of Clinical Research Professionals ▯ acrpnet.org

ACRP

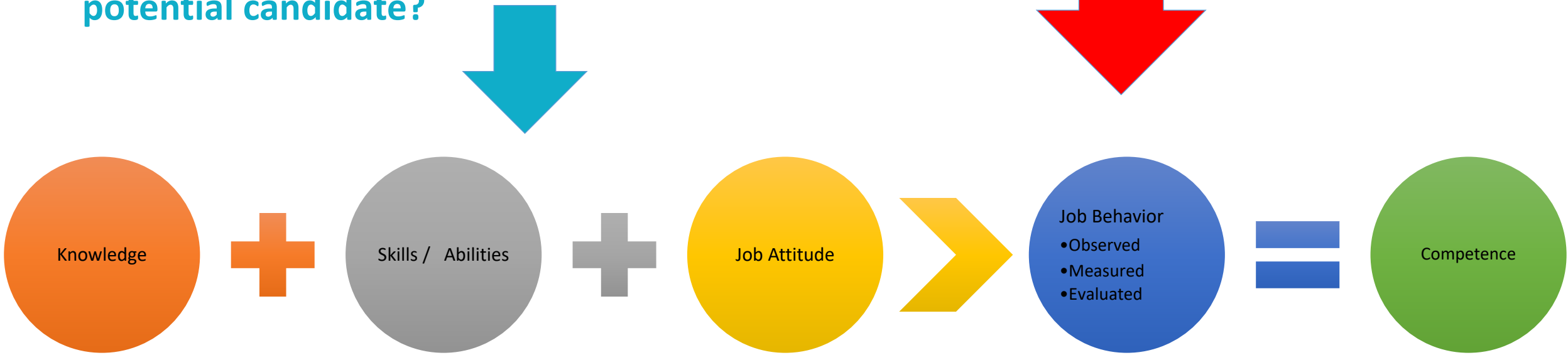
What's Different About Competency-Based Hiring?

- Typical Approaches
  - Generally focuses on the knowledge, skills and technical qualifications (the "K and S" parts of the equation)

- Competency-Based Hiring
  - Adds in an analysis of the behavioral characteristics, personality attributes, and individual aptitudes of the candidate (the "A" parts of the equation)
  - Further segments the "A"s into job-specific competencies (how well they will perform in a job) as well as organizational competencies (how well they will fit within an organization and it's culture)
  - Emphasizes the systematic definition of the competency requirements and ways to evaluate the competencies

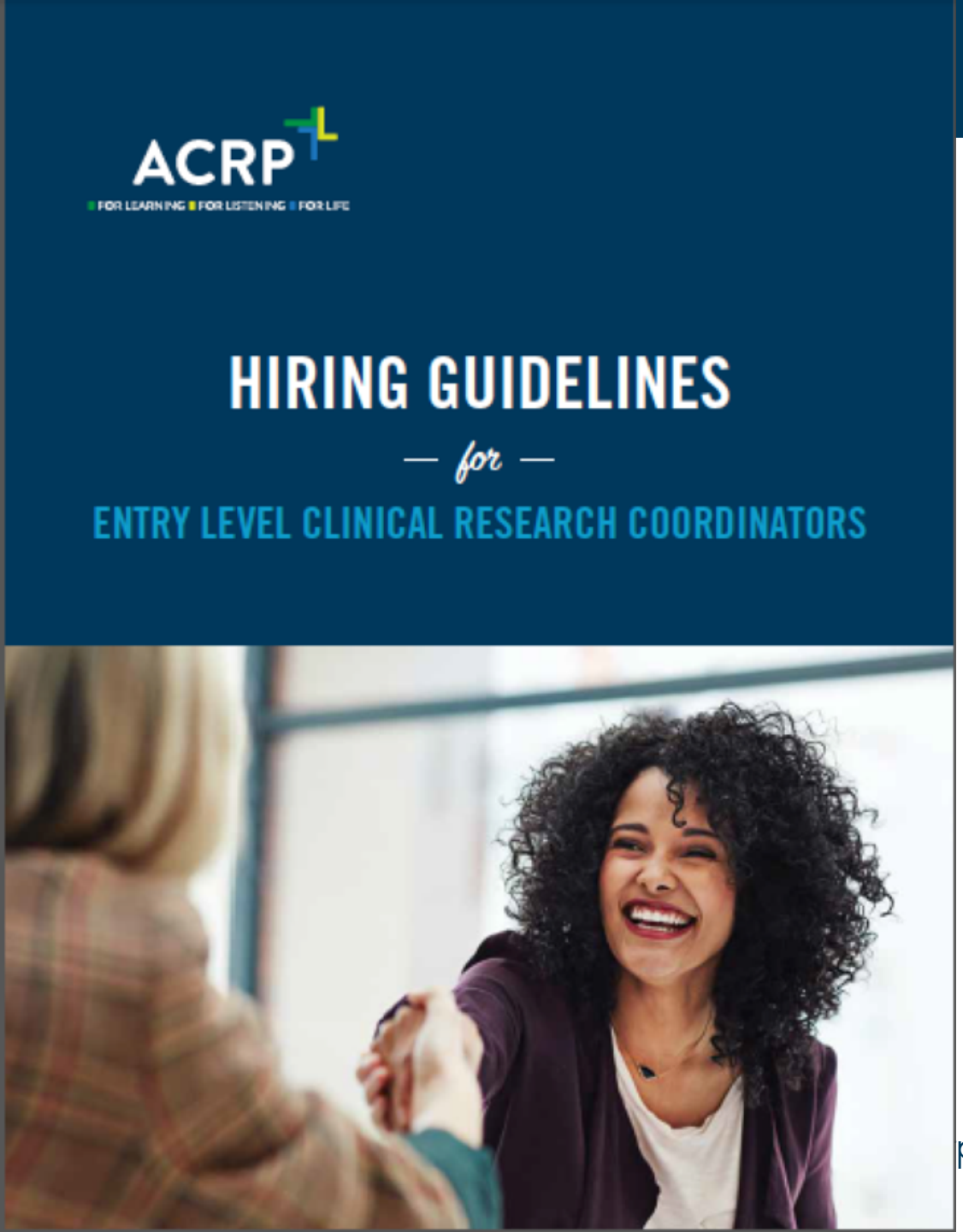
To take the most advantage out of competency based approaches, we should always be thinking about how we will measure the job performance!

So how can a hiring manager measure the KSA's of a potential candidate?



© Association of Clinical Research Professionals ⍰ acrpnet.org

ACRP



- ACRP recently (Dec 2018) published new competency-based hiring guidelines for entry-level CRCs.
- Many of the competencies apply to other roles as well
- We will continue to refine and develop guidelines for other roles as prioritized by our Workforce Innovation Steering Committee (WISC)
- These are available at:
  - https://www.acrpnet.org/resources/hiring-guidelines-for-entry-level-clinical-research-coordinators/

ACRP

Competency-Based Promotion and Advancement

© Association of Clinical Research Professionals | acrpnet.org

ACRP

Competency Based Performance Assessment / Reviews

- Provide a more detailed and nuanced understanding of the behaviors necessary for success
- Foster open communication between a supervisor and employee because these types of reviews require employee introspection / self-assessment as well as supervisor observation
- Provide more actionable and constructive feedback for the employee
- Aim to link the objectives and the competencies in a very clear, transparent way so employees can
  - See the career-progression or promotion pathway and what it will take to advance
  - See exactly where their gaps are and what they need to focus on to advance

© Association of Clinical Research Professionals acrpnet.org

ACRP

Example Competency Guidelines / Assessment Tool (1)

Core Competencies and Relevant Tasks								
Entry Level CRC			**Intermediate CRC**			**Senior CRC**		
The entry level CRC competencies focus on the ability to perform basics tasks and exhibit the knowledge of key aspects of clinical research at an essential or foundational level. For the most part, it is presumed that the entry level CRC will evolve in their ability to move from a basic level of understanding to the ability to perform a variety of tasks under direct supervision. It is anticipated that the entry level CRC will gradually be exposed to, and have the opportunity to demonstrate their competencies across several different types of clinical studies (investigational products, study phases, therapeutic areas and indications). Key behavioral competency descriptors include: define, describe, list and explain.			In addition to having mastered the competencies of the entry level CRC, the intermediate level CRC should be able to perform tasks independently, consistently and accurately, and demonstrate that they have achieved a moderate level of expertise in all of their skills and abilities resulting in high quality work. It is presumed that the intermediate CRC is able to apply their skills to a broad range of different types of clinical studies, navigate available resources appropriately, effectively use all tools and job aids at their disposal and operate e-clinical technologies with a reasonable degree of proficiency. Intermediate level CRCs can perform the majority of tasks independently and perform quality checks of their work. Intermediate level CRCs also know where and how to identify appropriate resources and support and are able to discern when to escalate issues needing additional intervention. Key behavioral competency descriptors include: demonstrate, implement, execute and use.			In addition to having mastered the competencies of the intermediate level CRC, the senior CRC demonstrates advanced skills and knowledge along with the ability to support, guide, train, demonstrate or lead study team members in the implementation of study related activities. The senior CRC applies critical thinking and creative problem solving skills across a wide variety of clinical studies. The senior CRC contributes to the development of new processes, procedures, tools and training to enhance clinical research activities across the competency domains and conducts quality assurance / quality control checks of the work of others. The senior level CRC continues to build on their competency foundation by making greater investments in their ongoing continuing education and professional development. Key behavioral competency descriptors include: Design, demonstrate, develop, evaluate, lead, guide and support.		
Total Domain Competencies Required	**114**	**114**	**Domain Competencies Required**	**114**	**114**	**Domain Competencies Required**	**114**	**114**
Total Domain Competencies Achieved	**0**	**0**	**Domain Competencies Achieved**	**0**	**0**	**Domain Competencies Achieved**	**0**	**0**
% of Total Domain Competencies Achieved	**0%**	**0%**	**% of Domain Competencies Achieved**	**0%**	**0%**	**% of Domain Competencies Achieved**	**0%**	**0%**

© Association of Clinical Research Professionals | acrpnet.org

ACRP

Example Competency Guidelines / Assessment Tool (2)

ACRP	Core Competency Guidelines for Clinical Research Coordinators (CRCs)								
Domain	Leadership and Professionalism: Encompasses the Principles and Practice of Leadership and Professionalism in Clinical Research								
	X when Proficiency / Competency is Achieved and/or Relevant Training Completed								
Level	Entry Level CRC			Intermediate CRC			Senior CRC		
General Competency Expectations	Explain the importance of professional conduct and describe leadership principles that impact the effective operation of an investigative site.	Self Assmt.	Mgr. Assmt.	Demonstrate an understanding of codes of conduct, conflicts of interest, professionalism and leadership as they relate to the role of the CRC.	Self Assmt.	Mgr. Assmt.	Demonstrate professionalism and apply basic leadership practices in all aspects of the role of the CRC.	Self Assmt.	Mgr. Assmt.
7.1 Describe and apply the principles and practices of leadership, management and mentorship in clinical research	*Differentiate between the roles and contributions of individuals serving in leadership, management and mentor capacities.*			*Demonstrate development in leadership skills through execution of clinical studies and contributions to site projects.*			*Contribute as a leader and peer-mentor within the site organization, supporting management in various tasks or responsibilities as appropriate including the development of less experienced study team members.*		
7.2 Identify ethical and professional conflicts associated with the conduct of clinical studies and implement procedures for their prevention or management	*Explain potential ethical and professional conflicts, identify ways in which these can be prevented and describe procedures to be followed should such occur.*			*Demonstrate an understanding of procedures to prevent potential ethical and professional conflicts and how to manage such events should they occur.*			*Develop standard operating procedures and best practices to mitigate the potential for conflicts in the conduct of clinical studies and develop procedures to be followed should such occur. Support and guide study team members in the event of occurrences of conflicts.*		
7.3 Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research	*Explain professional guidelines and code of ethics as they apply to the role of the CRC.*			*Demonstrate the ability to apply professional guidelines and codes of ethics to enhance clinical study execution.*			*Develop SOPs, guidelines, work instructions and training procedures and materials to convey the professional guidelines and codes of ethics for study team members to enhance the ethical and quality conduct of studies at the site.*		

© Assoc

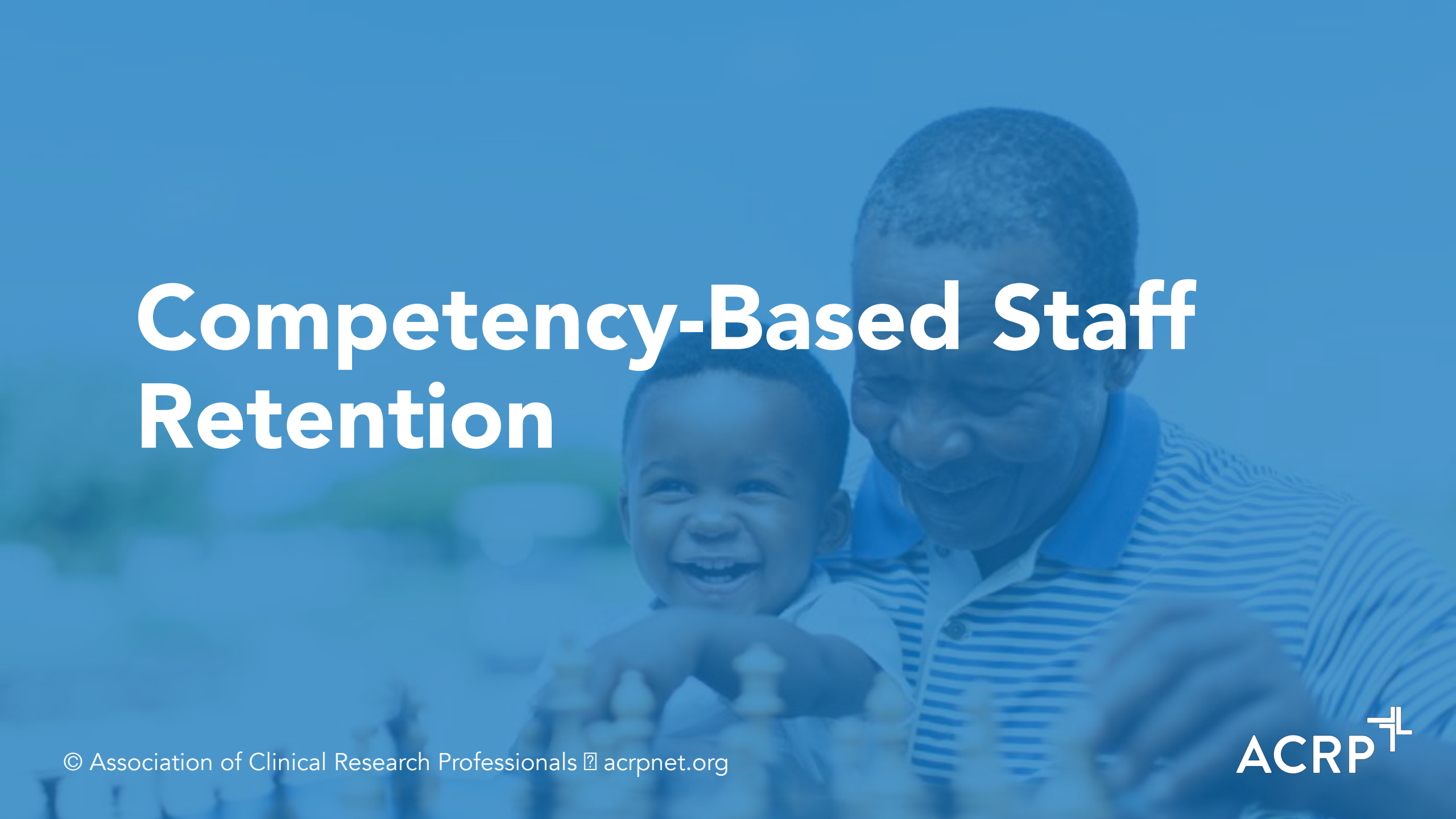
Role-Based Competency Guidelines

- Developed
  - CRA / Study Monitoring (2017)
  - Clinical Research Coordinators (CRC)s (2018)
- In progress
  - PI Competency Guidelines
  - CRA – Revisions
  - Technology / Data Analytics – competency survey
- You can learn more and download the guidelines here:

https://www.acrpnet.org/about/acrp-initiatives/

© Association of Clinical Research Professionals | acrpnet.org

Competency-Based Staff Retention

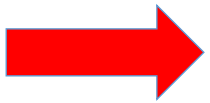


© Association of Clinical Research Professionals | acrpnet.org

ACRP

Did You Know?

- The primary paths to job turnover are:
  - Employee dissatisfaction
  - Better alternatives
  - A planned change
  - A negative experience



Additional predictors of turnover that merit careful attention include:

- Organizational commitment and job satisfaction.
- Quality of the employee-supervisor relationship.
- **Role clarity.**
- Job design.
- Workgroup cohesion.

Source: https://www.shrm.org/resourcesandtools/tools-and-samples/toolkits/pages/managingforemployeeretention.aspx

© Association of Clinical Research Professionals ▯ acrpnet.org

ACRP

Did You Know?

- The top 5 factors leading to employee satisfaction are:
  - Respectful treatment of all employees at all levels;
  - Compensation/pay;
  - Trust between employees and senior management;
  - Job security; and
  - Opportunities to use their skills and abilities at work

Source: https://www.shrm.org/resourcesandtools/tools-and-samples/toolkits/pages/managingforemployeeretention.aspx

© Association of Clinical Research Professionals ▯ acrpnet.org

ACRP

Competency Based Retention Practices

- Can reduce turnover because
  - Employees are made aware from the very beginning which behaviors and skills are needed to excel in a particular position.
  - They provide a way to recognize and reward high talent and excellent performance on a continual basis – not just annually. Such regular recognition keeps motivation levels high, which also improves retention.
  - They involve the employee in the process which ensures they feel more empowered in their own career growth

© Association of Clinical Research Professionals acrpnet.org

ACRP

Retention Best Practices – It's All About the Fit

- Competency – Expectations Fit
- Motivational Fit
- Cultural Fit
- Others?

Wrap-Up

© Association of Clinical Research Professionals | acrpnet.org

ACRP

Competencies Can Help Organizations / Managers By:

- Standardizing the development of competency-based **job descriptions** for different roles and skill levels
- Development of structured, competency-based **hiring guidelines**
- Creation of competency-based **training programs**
- Development of **competency based advancement and promotion programs**
- A structure for systematically evaluating and assessing proficiency and competencies to help in competency-based **job performance reviews and promotions**

© Association of Clinical Research Professionals ▯ acrpnet.org

ACRP

Competencies Can Help Individuals By:

- Providing a more standard way to develop **CV / Resume / Job Profiles** that highlight transferrable competencies and will be recognized by future employers
- **Self-assessment** of competencies to achieve next level of proficiency for a given job role
- **Identification of gaps** to prioritize and direct additional training activities
- **Accelerate and support promotion opportunities** through more objective and evidence-based discussions with management that are focused on competency achievement and not solely on job tenure

© Association of Clinical Research Professionals ▯ acrpnet.org

ACRP

Closing Thoughts

- A competency-based approach to career development:
  - Is necessary and important to ensure the quality of clinical research
  - Will enable a more sustainable workforce
  - Is gaining traction through the efforts of the JTF, ACRP and others
  - Ensures that you are best positioned to hire the best talent and grow and advance in your career!

© Association of Clinical Research Professionals acrpnet.org

Did We Meet Our Objectives?

At the end of this session you should be able to:

- Identify the elements that contribute to competency
- List the JTF (Joint Task Force) Harmonized Competencies for Clinical Research Professionals and discuss how they can be used for career / employee development
- Discuss the current initiatives and resources available through ACRP to promote a more competent workforce
- Describe ways that you can apply competency based approaches to your own career progression as well as within your organization

© Association of Clinical Research Professionals acrpnet.org

ACRP

Any Questions or Comments?

© Association of Clinical Research Professionals | acrpnet.org

Thank you!

Beth Harper, BSOT, MBA
beth.harper@acrpnet.org

© Association of Clinical Research Professionals ▯ acrpnet.org

ACRP