Redesigning Initial Onboarding to Begin with Foundational Clinical Research Knowledge

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1. Background
OHSU Knight Cancer Institute (KCI) provides clinical research specific onboarding to new clinical research staff, covering topics related to research operations and processes involved in coordination, regulatory work, and data management. Two full-time clinical research trainers support this program by conducting 15-20 individual or small group training sessions per week. The target timeline for an individual's onboarding completion is 150 days, achieved by attending 1-2 training sessions per week.

Feedback from clinical research staff indicates the need for a revised onboarding program, including:
- Lengthy onboarding timelines
- Insufficient role preparedness
- Training gaps due to differences in team-specific processes
- Inadequate alignment between training timelines and practical application

2. Goals
Revise onboarding program to implement Foundational Training, consisting of three key pillars:
- Building essential clinical research knowledge
- Teaching resourcefulness and self-sufficiency
- Standardizing the training process across all study teams

3. Solutions and Methods
In August 2023, the lead Clinical Research Trainer formed a working group (WG) comprised of three Disease Team Managers, a Program Director, Clinical Research Operations Manager, Research RN and Administrative Coordinator. Together, the WG identified essential topics and discussed the curriculum restructuring necessary to support this new approach.

Once curriculum content is finalized, current onboarding content will be replaced. Additionally, the WG will ensure standardization and best practice reinforcement by presenting materials at regularly scheduled Continuing Education Sessions (CES). These sessions are available to all KCI clinical research staff in real time, with materials and session recordings published for future reference.

4. Outcomes
The WG has identified several essential topics for Foundational Training, each including subtopics that address role-specific tasks. The overarching topics include basic terminology, general cancer education, protocol comprehension, data integrity, patient safety, and oversight.

The WG identified source documentation as its first focus area. Using the AACI Good Documentation Practices template language, the WG updated the internal source documentation training material. After vetting by members of the leadership team, the education team, and internal monitors, the final version was recently presented at a CES and made available to all clinical research staff via intranet.

The WG is currently working on content for two overarching topics: basic terminology and general cancer education. A glossary has been drafted, including all basic terminology definitions and acronyms

encountered during Foundational Training and found in work instructions. An outline of general cancer education topics has been drafted and is currently being edited by the WG.

5. Lessons Learned and Future Directions
The WG continues to develop training content to address the remaining topics and subtopics. To ensure accuracy and relevancy, supervisors and team representatives now provide a rigorous review prior to finalization. Once complete, trainings will be released as electronic, on-demand training modules that record completion and comprehension.

When all content creation has concluded, and an appropriate topic timeline established, the Foundational Training onboarding structure will be implemented starting with a small advisory group comprised of new and expert clinical research staff. This group will provide formal feedback highlighting any additional adjustments needed.