<u>Comprehensive Application of Supplemental Phantom Educational Resources (CASPER): a Friendly Phantom Patient to Guide the Way for New Study Coordinators</u>

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1. Background

The clinical trials office (CTO) at the Barbara Ann Karmanos Cancer Institute, an NCI-Designated Comprehensive Cancer Center, created an enhanced formal orientation program (EOP) in December 2016 for all new employees. This program consists of 22 modules that review the basics of oncology, clinical trials, different research departments, and role-specific topics for eight weeks prior to the coordinators starting their own workloads. So far, 37 groups (over 200 employees) have completed the EOP. Orientees are given a post-orientation survey that asks what they liked about the program and how it can improve. Multiple groups expressed a desire for more interactive modules to reinforce the instruction.

2. Goals

- Address repeated requests from orientees to follow a patient through the trial process
- Allow hands-on practice for new CTO study coordinators (SC), including review of patient documents for study related procedures
- Promote greater familiarity with study processes, which will increase SC proficiency
- Provide examples of tools (adverse event, deviation, and medical history logs, emails to physicians, and note-to-file templates)

3. Solutions and Methods

Three interactive phantom patient modules (PPM) (introduction, informed consent, eligibility review and registration; deviations, tumor tracking, adverse events; source document creation, EMR exposure, and protocol treatments, with all modules reviewing applicable policies) were created to supplement the EOP. The PPM are attended in tandem with the EOP to allow SCs to become familiar with the processes introduced in the modules. To ensure comprehensive exposure, three studies were chosen to represent a broad spectrum of disease types, treatment methods, and sponsor variety. The PPM follows three phantom patients through their respective studies to reinforce the instruction of the EOP. In order for SCs to review the patient specific study procedures, each phantom patient has a corresponding shadow chart that utilizes information from real patients, who have enrolled on these studies. The redacted shadow charts were uploaded into Microsoft Teams and Veeva Site Vault to protect PHI.

4. Outcomes

The PPM were implemented in February 2022 and included employees who recently completed the EOP to gather thorough feedback. Positive feedback was received from participants, indicating they feel more comfortable with the eligibility and registration process and have learned new ways to navigate the EMR. Follow-up with participants and their supervisors is planned in order to determine if there is a greater understanding of the CTO processes once the participant receives their workload. The goal is for SCs to feel more competent and comfortable in their role.

5. Lessons Learned and Future Directions

Initially it was planned to incorporate the phantom patient charts into preexisting modules; however, it was determined that separate PPM would be more beneficial to the orientees.

After presenting the first module, an introduction session was created, which provides more in-depth instructions regarding expectations and the location of documents needed during the PPM. Creating a stand-alone introduction module will also allow more time to be spent on the eligibility and registration process in the first session.