Category: Training, Career Development, and Staff Retention – Completed project

Streamlining Investigator Training and Authorization

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1. Background

Huntsman Cancer Institute (HCI) is a vibrant and growing National Cancer Institute (NCI)-designated comprehensive cancer center with over 120 physician investigators, 40 advanced practice clinician sub-investigators, and a portfolio of more than 550 active clinical trials. With multiple steps and individuals involved in the training and onboarding of new investigators, we recognized a need to implement a more streamlined and accelerated process to deliver and track the training and authorization for investigators. The process needed to clearly outline all requirements and provide detailed instructions for investigator training and authorization, including quality assurance checks. Additionally, we had to incorporate an effective mechanism for tracking and documenting all required training to ensure completion both initially, and at ongoing intervals in the future.

2. Goals

1. To compile all training requirements and platform links in one location with clear instructions for investigators in a Training Brochure.
2. To define and implement a streamlined, collaborative process for the training and authorization of all investigators involved in clinical research at HCI.
3. To create a detailed tracking system to capture training and expiration dates, and authorization status.

3. Solutions and Methods

We began by reviewing all institutional training requirements and platforms and drafted a comprehensive Training Brochure with instructions and links. Next, we identified roles responsible for each step of the process from notification of a new investigator joining HCI through commencement of their work on clinical trials. The process was mapped out as follows:

- The Clinical Trials Office (CTO) Training Administrator is notified of new investigators by clinical educators and faculty coordination managers.
- Once notified, the CTO Training Administrator sends an introduction email with the training brochure attached.
- Upon completion of training, new investigators send all required training documents to the CTO Training Administrator who conducts a quality check and assessment for authorization.
- Once authorized, the CTO Training Administrator notifies the investigator, study teams, and other necessary stakeholders triggering these subsequent steps:
    - NCI investigator registration/transfer and NCI Cancer Therapy Evaluation Program (CTEP) access
    - Training and delegation on the relevant clinical trial research group portfolio
    - Account creation for the clinical trials management system (CTMS) and Adobe Sign, HCI's platform for Part 11 compliant electronic signatures
    - New investigator training and orientation with the CTO Medical Director (for physician investigators)
    - Invitation to the 'How to be a Principal Investigator' training workshop conducted by seasoned investigators and leaders from HCI and the University of Utah

- Throughout the training and authorization process, a detailed spreadsheet is used to track completion dates of required training and investigator authorization status.

4. Outcomes

Implementing our streamlined process, enhanced by improved communication and effective documentation of investigator training and authorization, has significantly improved efficiency and compliance in onboarding new investigators at HCI.

5. Lessons Learned and Future Directions

We will continue to utilize this process as we search for ways to further refine and automate.