*Category: Trial Start Up/Closure – Work in Progress*

**Improving Efficiency and Time Management during the Site Selection Process: A Collaborative Approach**

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**1. Background**

Prior to site selection, Cancer Centers receive multiple requests for information from sponsors and their contract research organizations (CROs) to assess site feasibility. Confirming a site's feasibility to conduct a clinical trial involves assessments in many areas including site logistics, technical capabilities, accrual potential, activation timelines and administrative infrastructure, and reviews of site-specific standard operating procedures. All of these areas require completion of lengthy questionnaires, gaining access to portals, multiple email conversations, and often times meetings in addition to required pre-site selection visits (PSSV). The requests for information and required questionnaires are extensive, time-consuming, and in many cases, duplicative.

**2. Goals**

Our goal is to streamline communication during the site selection process to work more efficiently and collaboratively with our sponsors and CROs. Another goal is ensuring accuracy and consistency of information provided during the site selection process.

We expect that by creating and maintaining a comprehensive document that provides our sponsors and CROs site-specific information and answers to frequently asked questions we will improve efficiency for all parties. The document will reduce time to confirmation of site selection, as well as the amount of time required during pre-site selection visits.

**3. Solutions and Methods**

We created a comprehensive new study start-up packet, that we provide to sponsors and CROs as soon as discussions related to site selection commence. The packet includes our site-specific study start-up requirements, activation timelines, technical capabilities, answers to frequently asked questions, and standard operating procedures. This comprehensive document helps our sponsors and CROs assess the feasibility of conducting clinical research at Huntsman Cancer Institute in a more efficient manner.

**4. Outcomes and Future Directions**

The unsolicited feedback received from sponsors and CROs has been positive. Most state they are able to complete the majority of their site selection reports with the data provided in the start-up packet prior to the PSSV. Now, time spent with the principal investigator and site study staff during the PSSV is spent more productively discussing study-specific recruitment strategies and protocol requirements, as well as addressing questions.

Site selection timelines appear to have improved, especially for our Phase I experimental therapeutics studies, primarily for participation in dose escalation where rapid site selection is necessary.

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Reports from our management team, as well as sponsors and CROs, have confirmed that providing the study start-up packet prior to the PSSV improves transparency, communication, and the sponsor-site relationship overall.

We will continue to collect feedback from sponsors and CROs to measure satisfaction.

We will continue to update the new study start-up documents as clinical research requirements and site-specific processes evolve.