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

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BACKGROUND
Cancer centers receive multiple requests for information from sponsors and their contract research organizations (CROs) to assess a site’s feasibility to conduct a clinical trial. This involves assessments in many areas:

• Site logistics
• Technical capabilities
• Accrual potential
• Activation timelines
• Administrative infrastructure
• Site-specific standard operating procedures

Gathering information in these areas requires lengthy questionnaires, access to portals, multiple email conversations, and meetings in addition to required pre-site selection visits (PSSVs). The requests for information and required questionnaires are extensive, time-consuming, and in many cases duplicative.

METHOD
• Our goal is to streamline communication during the site selection process to work more efficiently and collaboratively with our sponsors/CROs as well as ensure accuracy and consistency of information provided during the site selection process.
• By creating and maintaining a comprehensive document with site-specific information and answers to frequently asked questions for our sponsors/CROs, we expect to improve efficiencies for all parties by reducing the time it takes to confirm site selection.

RESULTS
We created a comprehensive new study start-up packet to give sponsors/CROs as soon as site selection discussions commence. The packet includes the following:

• Site-specific study start-up requirements
• Activation timelines
• Technical capabilities
• Answers to frequently asked questions

We provide this comprehensive document to our sponsors and CROs to help them assess the feasibility of conducting clinical research at HCI in a more efficient manner.

CONCLUSIONS
• The feedback 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 our site-specific study start-up packet prior to the PSSV.
• Time with the principal investigator and site study staff during the PSSV can now be spent more productively, addressing questions and discussing study-specific recruitment strategies and protocol requirements.
• Site selection timelines appear to have improved, especially in our Phase I experimental therapeutics space, where rapid site selection is necessary, primarily for participation in dose escalation.
• Internal reports from management as well as sponsors and their CROs have confirmed that providing the study start-up packet prior to the PSSV allows for transparency, which improves communication and the sponsor/site relationship overall.

FUTURE PLANS
• Create and implement sponsor/CRO surveys to confirm feedback received to date and measure satisfaction
• Begin discussion with CROs/sponsors regarding creation of databases to capture site-specific study start-up requirements, activation timelines, technical capabilities, and answers to frequently asked questions
• Continue to update the New Study Start-up Documents as clinical research requirements and site specific processes evolve