*Category: Resource Management and Finance – Completed project*

**Central Resource Management to Facilitate Expanded Access Use of Investigational Products**

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**1. Background**

Expanded access treatment, also called compassionate use or single-patient investigational new drug (IND), is a potential treatment pathway for patients with serious or life-threatening disease who have exhausted all available treatments and are not eligible for a clinical trial. Although these uses are not clinical research, they follow similar pathways for obtaining necessary regulatory approvals and providing oversight for participants, including informed consent.

We continue to receive requests for expanded access use of investigational products, both intermediate and single-patient use, as treatments become more targeted. Most often, these requests are urgent, if not emergent. For our patients, there is a clear need to address and prioritize requests efficiently. Expanded access protocols are different from usual clinical trials processes. At times, this has caused confusion among study teams, making it unclear if the treatment should be managed from a clinical care or research support standpoint and which resources should be allocated. Expanded access treatments still require safety reporting to the drug manufacturer, so it is important to ensure study teams understand what is expected from them.

**2. Goals**

- Create a centralized process to ensure all relevant stakeholders are involved from first knowledge of an expanded access use request
- Allocate and prioritize resources appropriately (i.e, Regulatory, Contracts, Pharmacy, etc.)
- Maintain safety and regulatory oversight from start to finish

**3. Solutions and Methods**

- Develop a central email notification list that includes relevant stakeholders who should be included in the initiation process
- Create a policy that defines review and approval of resource allocation, including approval by Huntsman Cancer Institute (HCI) senior research leaders before initiation
- Outline responsibilities and specific resource needs based on the type of request (single patient versus multi-patient)
- Train research staff in expanded access protocols, the review process, and requirements for managing these protocols
- Register and maintain patient records in OnCore
- Create an electronic case report form (eCRF) for tracking safety events in our electronic data capture (EDC), which is verified through routine monitoring

**4. Outcomes**

- This new process facilitates communication among stakeholders and defines responsibilities early
- This process provides ongoing training and compliance oversight to ensure safety and regulatory compliance

- Time spent to review and set priorities early in the process has enabled us to know which requests are less urgent
- We have encouraged feasibility review where appropriate and may negotiate with the provider of the investigational product to cover the use of additional resources outside of a clinical trial

**5. Lessons Learned and Future Directions**

This is a coordinated effort that requires clear communication and knowledge of the process.

- Each request for expanded access is different
    - No matter how much we standardize the process, adaptability is important
- We receive expanded access requests in many ways
    - Getting the word out about the central notification pathway is key
    - We continue to look for options for providers to make their requests
- Educating providers and staff on the available resources and their role in the process has helped in receiving earlier notification and facilitation
- We are working with the hospital to pay for a portion of an full-time equivalent (FTE) in Regulatory and portion of an FTE in the Clinical Trials Office to coordinate these treatment protocols

**Figure**