1. PURPOSE

The purpose of this document is to describe processes that should be considered when requesting access to an investigational product being developed and supplied by an entity outside the institution. This entity could be a company, academic center, or service provider. Ultimately, this entity represents the manufacturer of the product and herein is referred to as manufacturer. This document includes information on how to identify an appropriate contact for requesting access, common manufacturer practices, and a list of documents that should be requested/obtained to support the expanded access request.

2. PROCESSES

2.1 Identifying Expanded Access Contacts

2.1.1 To identify the appropriate contact for the Expanded Access request, institutional staff may wish to consider the following resources:

2.1.1.1 Project Facilitate: https://www.fda.gov/about-fda/oncology-center-excellence/project-facilitate The Oncology Center of Excellence Project Facilitate call center is a pilot program to assist oncology healthcare providers or regulatory professionals in requesting access to investigational therapies for patients with cancer.

2.1.1.2 Expanded Access Navigator: http://navigator.reaganudall.org/ this website provides a roadmap to guide patients, caregivers, and physicians through the expanded access request process. The website includes a drug company directory that includes links to company policies on Expanded Access and provides summary information about timeline for company acknowledgement of an Expanded Access request.

2.1.1.3 ClinicalTrials.Gov: https://clinicaltrials.gov/ this website provides a database of privately and publicly funded clinical studies conducted around the world, including Expanded Access programs. It is possible to find existing Expanded Access programs and initiate contact.

2.2 Common Manufacturer Practices

2.2.1 The individual responsible for contacting the manufacturer and gaining authorization of the expanded access use should be aware that many manufacturers require a specific form or application to be completed. The physician sponsoring the request should be involved in completing any requested documentation.

2.2.2 Until the manufacturer agrees to the request, it is advised that minimal action be taken on an expanded access request.

2.2.2.1 In cases where the manufacturer denies the request, the investigational product may not be utilized to treat the patient.

2.2.2.2 In cases where the manufacturer agrees to the request, additional documentation should be requested to aid in the preparation and submission of regulatory applications. See section 2.3 for a list of documents and their use.

2.2.2.2.1 It is common practice manufacturers to request final approved versions of documents for their records. As applicable, final approved documents that

incorporate changes made at the request of the manufacturer, IRB, or FDA should be sent to the manufacturer when requested.

2.3 Documents to Request

The following documents will aid in the preparation and submission of regulatory applications to oversight committees, including the FDA and IRB, and should be requested from the manufacturer upon authorization to use the requested product under expanded access.

2.3.1 Letter of Authorization or Letter of Concurrence

If the physician or institution is sponsor of the expanded access application (i.e., submits the regulatory application to the FDA), a Letter of Authorization (LOA, also called a letter of cross-reference) for drug submissions or a Letter of Concurrence for device submissions should be requested from the manufacturer. This letter will need to be included in the IRB and FDA applications.

2.3.2 Investigational Product Information

If available, obtain a copy of the pharmacy manual, Investigator's Brochure (IB), user manual, instructions for use, or other applicable materials on use of the investigational product. This information should be provided to the treating physician and a copy sent to applicable staff (e.g., investigational pharmacy) and oversight committees (e.g., IRB).

2.3.3 Treatment Plan or Protocol Template

Request a treatment plan or protocol template and confirm whether the manufacturer needs to approve the final plan. These documents should be shared with the treating physician and other applicable staff for development of final documents.

2.3.4 Informed Consent Template

Request an informed consent template and confirm whether the manufacturer needs to approve the final form. These documents should be shared with the treating physician and other applicable staff for development of final documents.