04- Contractual Agreements

Expanded Access Standard Practices and Procedures

Scope: All Expanded Access

TRANSFORMING EXPANDED ACCESS TO MAXIMIZE SUPPORT AND STUDY

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1. PURPOSE

The purpose of this document is to describe legal agreements 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.

2. Legal Agreements

Institutional staff processing expanded access requests should consult with their institutional legal/contracts office to ensure proper agreements are in place for the expanded access use.

2.1.1 Confidential Disclosure Agreements

2.1.1.1 Institutions may wish to put into place a confidential disclosure agreement (CDA) with the manufacturer to ensure protection of all confidential information, including individually identifiable health information.

2.1.1.2 Unless a CDA has been put in place, all communications with the drug manufacturer should be redacted of individually identifiable health information, including the 18 HIPAA identifiers that are considered personally identifiable.

2.1.2 Expanded Access Use Agreements

2.1.2.1 A clinical trial agreement or clinical treatment plan agreement may be required or recommended by the manufacturer providing the investigational product.

2.1.2.2 It can be helpful for legal/contract offices to develop template agreements that are tailored to expanded access and offer these templates in their contractual negotiations.