# Appendix: Expanded Access

## When to Use this Form

This form should be used to apply for IRB approval for use of drugs or devices under a treatment use, or other FDA regulated non-emergency uses of unapproved drugs or devices outside of an established clinical trial.

Complete all applicable elements contained in this form when approval from the sponsor and FDA has been received or is pending for the proposed use for a Treatment IND, Treatment IDE, Compassionate Use IDE, Humanitarian Use Device (HUD), or other FDA approved expanded access use.

## Submission Instructions

#### The FDA requires the following elements to issue a Treatment IND

1. The drug is intended to treat a serious or immediately life-threatening disease;

2. There is no comparable or satisfactory alternative drug or other therapy available to treat that stage of the disease in the intended patient population;

3. The drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed; and

4. The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence

Approval from the sponsor and FDA for the proposed use is attached/pending.

#### The FDA requires the following four conditions to consider the use of an investigational device under a Treatment IDE

1. The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition;

2. There is no comparable or satisfactory alternative device or other therapy available to treat or diagnose that stage of the disease or condition in the intended patient population;

3. The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or such clinical trials have been completed; and

4. The sponsor of the investigation is actively pursuing marketing approval/clearance of the investigational device with due diligence

Approval from the sponsor and FDA for the proposed use is attached/pending.

#### Compassionate Use IDE: an IDE supplement submitted to the FDA for approval should contain the following

A description of the patient's condition and the circumstances necessitating treatment

A discussion of why alternatives therapies are unsatisfactory and why the probable risk of using the investigational device is no greater than the probable risk from the disease or condition

An identification of any deviations in the approved clinical protocol that may be needed in order to treat the patient; and

The patient protection measures that will be followed. (Informed consent, concurrence of IRB chairperson, clearance from the institution, independent assessment from uninvolved physician, authorization from IDE sponsor)

Approval from the sponsor and FDA for the proposed use is attached/pending.

#### Humanitarian Use Device: FDA must grant HUD status and approve a Humanitarian Device Exemption (HDE) for a device to be approved as an HUD

HUD application/approval

HDE application/approval

Sponsor and FDA approval for the proposed use is attached/pending

#### Other FDA approved expanded access use for a drug/biologic/device:

For situations where the FDA has approved another type of expanded access use for patients, include communications with FDA, the approval letter, and related information submitted that describes or supports the type of patient, use, and protections involved in the expanded access use.

Approval from the sponsor and FDA for the proposed use is attached/pending.

## Full Board Review

These expanded access use submissions require full board review. For full details on categories of IRB review, visit our website.

## Treatment

|  |  |
| --- | --- |
| Investigational Device(s) | |
| This treatment use includes | N/A (drug only)  A significant risk device  A non-significant risk device  Treatment IDE  Compassionate IDE  Humanitarian Use Device HUD  Other FDA approved expanded access use; describe: |
| “Significant risk” and “non-significant risk” are FDA classifications.  NOTE: you must submit to the IRB the following forms of documentation in addition to the IDE/HUD number:   * *Communication from the FDA for IDE approval* * *Written Communication from the Sponsor for IDE approval* * *Sponsor Protocol* * *Informed Consent document* * *Investigator’s Brochure* * Package Insert | |
| Investigational Drug(s) | |
| This treatment use includes | N/A (device only)  An FDA approved drug for indication and population  A drug for off-label purpose  An investigational drug-population  An investigational drug  A placebo  Other FDA approved expanded access use; describe: |
| Note: you must submit to the IRB the following forms of documentation in addition to the IND number:   * *Communication from the FDA for IND approval* * *Written Communication form the Sponsor for IND approval* * *Sponsor Protocol* * *Informed Consent document* * *Investigator’s Brochure* * *Package Insert* | |