INVESTIGATIONAL DEVICE COMPASSIONATE USE CHECKLIST

Children's Hospital of Philadelphia RESEARCH INSTITUTE

Compassionate use of investigational devices may be considered in patients based upon specific criteria detailed in the Code of Federal Regulations (CFR) part 812 guidelines. The following information and checklist are intended to help investigators planning to use an investigational device under FDA compassionate use guidelines.

Definition of Compassionate Use: Use of an investigational device to diagnose, monitor or treat an individual patient or small group of patients with a serious disease or condition when there are no available alternative options.

Criteria for Investigational Device Compassionate Use:

1. The patient has a life-threating or serious disease or condition
2. There is no comparable or satisfactory alternative therapy to diagnose, monitor or treat the disease or condition
3. Potential patient benefit justifies the potential risks of the investigational device

Depending on whether or not there is an Investigational Device Exemption (IDE) for a clinical trial for the device, there are two regulatory pathways governing compassionate use:

1. There is an IDE for the device, or
2. There is no IDE for the device.

Complete either the checklist "Under an IDE", or the checklist "Not Under an IDE" to ensure that the essential elements of FDA compassionate use device guidelines are met.

Proposed Device Use Under an FDA IDE

The IDE Sponsor, who may be the device manufacturer or the physician who has submitted the IDE, should submit an IDE supplement to the FDA requesting approval for a compassionate use under section 812.35(a) to treat the patient. FDA must approve before proceeding with use.

The supplement should include:

• A description of the patient's condition and circumstances requiring treatment, diagnosis or monitoring	☐ Not Done	☐ Done
• Discussion of reasons why alternative therapies are unsatisfactory	☐ Not Done	☐ Done
• Discussion of why the probable risk of using the investigational device is no greater than the probable risk from the disease or the condition	☐ Not Done	☐ Done
• Describing any deviations in the approved clinical protocol that may be needed to treat the patient	☐ Not Done	☐ Done
• The patient protection measures that will be followed: 1. Draft of the informed consent to be used 2. Concurrence by the IRB chairperson 3. Independent assessment by uninvolved physician 4. Authorization from device manufacturer on the use of the device	☐ Not Done	☐ Done

Requirement for follow-up report:		
• Follow-up report submitted by person who submitted the initial compassionate request: 1. Follow-up report to be submitted within 45 days of device use 2. Report to contain summary of patient outcome 3. If any problems occured as a result of using the device, this should be discussed in the follow-up report, and reported to the IRB	☐ Not Done	☐ Done

Proposed Device Use NOT Under an FDA IDE

A compassionate use request for a single patient may be submitted by the physician or maufacturer with the information outlined in "The supplement should include", above, to the FDA, along with a description of the device provided by the manufacturer, to the following address:

Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave
Document Control Center
W066 Rm G-609
Silver Spring, MD 20993

Physicians and manufactures can contact CDRHExpandedAccess@fda.hhs.gov for assistance.

Requirements for compassionate use not under an IDE:

• Provide confirmation that the patient will not be treated until the FDA approves use of the device under the proposed circumstances.	☐ Not Done	☐ Done
• Provide information that includes preliminary evidence of safety and effectiveness that justifies such use, and whether such use would interfere with the conduct of a clinical trial to support marketing approval.	☐ Not Done	☐ Done
• Provide an appropriate schedule for monitoring the patient, taking into consideration the investigational nature of the device and the specific needs of the patient. The patient should be monitored to detect any possible problems arising from the use of the device.	☐ Not Done	☐ Done
Requirement for follow-up report:		
• Follow-up report submitted by person who submitted the initial compassionate request: 1. Follow-up report to be submitted within 45 days of device use 2. Report to contain summary of patient outcome 3. If any problems occured as a result of using the device, this should be discussed in the follow-up report, and reported to the IRB	☐ Not Done	☐ Done

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