

**SEATTLE CHILDREN'S RESEARCH INSTITUTE  
OPERATING POLICIES / PROCEDURES**

<b>DEPARTMENT:</b>	Institutional Review Board
<b>POLICY NUMBER:</b>	IRB-040
<b>REPLACES:</b>	New Policy
<b>EFFECTIVE DATE:</b>	February 09, 2010
<b>REVISION DATE:</b>	New Policy

**TITLE:** Compassionate Use of an Investigational Device

**SUMMARY:**

“Compassionate use” allows access to investigational devices for patients who do not meet the requirements for inclusion in a clinical investigation but for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition.

FDA recognizes that there are circumstances in which an investigational device is the only option available for a patient faced with a serious, albeit not life-threatening condition. In these circumstances, FDA uses its regulatory discretion in determining whether compassionate use of an investigational device should occur.

Unlike emergency use of an unapproved device, prior FDA approval is required before compassionate use occurs. (Section 561(b) of the act and 21 CFR 812.35.) If a patient's condition deteriorates while FDA approval is pending, please consult the “Emergency Use” procedures for investigational devices.

Once the FDA approves the compassionate use, the clinician must seek concurrence from the IRB Chair to proceed with the device for patient treatment. This policy/procedure includes the detailed information that the Seattle Children's IRB will follow regarding compassionate use of investigational devices.

**POLICY/PROCEDURE:**

**040-1 FDA Submission: IDE Supplement**

040-1.1 In order to obtain FDA approval, the clinician (either through the industry sponsor or directly) should submit an IDE supplement requesting

approval for a protocol deviation under section 812.35(a) in order to treat the patient under compassionate use. The IDE supplement should include:

040-1.1.1 A description of the patient's condition and the circumstances necessitating treatment;

040-1.1.2 A discussion of why alternative 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;

040-1.1.3 An identification of any deviations in the approved clinical protocol that may be needed in order to treat the patient; and

040-1.1.4 The patient protection measures that will be followed. These measures include:

- a. Informed consent from the patient or a legal representative;
- b. Clearance from the institution (additional details are provided below);
- c. Concurrence of the IRB chairperson (additional details are provided below);
- d. Documentation of an independent assessment from an uninvolved physician; and
- e. Authorization from the IDE sponsor, if an approved IDE exists for the device.

040-1.2 **The clinician should not treat the patient identified in the supplement until the FDA approves use of the device under the proposed circumstances.** In reviewing this type of request, FDA will consider the above information as well as whether the preliminary evidence of safety and effectiveness justifies such use and whether such use would interfere with the conduct of a clinical trial to support marketing approval.

## 040-2 Clearance from the Institution

040-2.1 IRB Approval: A sponsor shall not use an investigational device at Seattle Children's until the IRB has approved the application or supplemental application.

- a. The sponsor must provide information about any ongoing clinical trials involving the device that are currently approved at Children's, and the relevant protocol that will be followed.
- b. If there is no ongoing clinical trial at Seattle Children's involving the device, the IRB must approve a protocol prior to implantation of the investigational device. Please contact the Human Subjects

Protection Program office for more information about the application process.

- 040-2.2 Submit the Compassionate Use Device Form for approval by the designated institutional officials in the following order:
- a. Pediatrician in Chief or Surgeon in Chief (as appropriate, depending upon the nature of the procedure and the service line involved);
  - b. Medical Director; and
  - c. Chief Financial Officer.

**040-3 Concurrence of IRB Chair for Compassionate Use**  
(in addition to IRB approval of clinical trial)

- 040-3.1 The clinician should send an email to [IRB@seattlechildrens.org](mailto:IRB@seattlechildrens.org) that includes the following documents and information:
1. A copy of the information submitted to the FDA for the compassionate use ("IDE Supplement");
  2. A copy of the protocol currently being used in an ongoing clinical trial;
  3. A copy of the consent form to be used with the participant;
  4. A copy of the FDA approval letter for the compassionate use;
  5. The estimated date of implantation;
  6. A copy of the approved Compassionate Use Device Form.

The IRB Chair may request additional information as needed.

**040-4 Patient Monitoring and Reporting Requirements**

- 040-4.1 If the request is approved by the FDA and IRB concurrence is obtained, the attending clinician should devise 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.
- 040-4.2 Following the compassionate use of the device, a follow-up report should be submitted to FDA as an IDE supplement in which summary information regarding patient outcome is presented (including any problems). When the follow-up report is submitted to the FDA, a copy should also be provided to the IRB office.
- 040-4.3 If any problems occurred as a result of device use, these should be reported to the Children's IRB as soon as possible.
- 040-4.4 Information about the compassionate use should be included in the IRB status report for the ongoing clinical trial at the time of continuing review.

#### **040-5 Compassionate Use for Multiple Patients**

The above compassionate use criteria and procedures can also be applied when a physician wishes to treat a few patients rather than an individual patient suffering from a serious disease or condition for which no alternative therapy adequately meets the medical need. In this case, the physician should request access to the investigational device through the IDE sponsor. The sponsor should submit an IDE supplement that includes the information identified above and indicates the number of patients to be treated. Such a supplement should include the protocol to be followed or identify deviations from the approved clinical protocol. As with single patient compassionate use, a monitoring schedule should be designed to meet the needs of the patients while recognizing the investigational nature of the device. Follow-up information on the use of the device should be submitted in an IDE supplement after all compassionate use patients have been treated.

**Submitting Office:** Institutional Review Board

#### **Approved by:**

\s\ Douglas Diekema, MD, MPH, 02/09/10  
Chair, Institutional Review Board

\s\ Laurie Bolton, JD, 02/09/10  
Director, Office of Institutional Assurance