Please refer to Appendix A-9 of the **Investigator Manual** (HRP-103) for more detailed information about emergency uses. At Seattle Children’s, “Right to Try” provisions under state and federal laws are implemented through the emergency use process. Sections A & B of this form should be emailed to the IRB representative (per HRP-103) and discussed **before** **the use, whenever possible**. The fully completed form **must** be submitted to IRB@seattlechildrens.org within **5 working days after initiation** of the emergency use.

**A. Physician Information**

|  |  |
| --- | --- |
| Treating Physician’s Name:       | Date:       |
| Department, Division:       | Phone/Pager:  |
| Email address:       | Preferred method of contact:       |

**B. Confirm that Emergency Use is Appropriate** (all 4 boxes must be checked)

|  |  |
| --- | --- |
| [ ]  1. Patient has a **life-threatening** or **serious disease or** **condition** (*see* HRP-103, Appendix A-9) for the definitions of these terms, which differ for drugs/biologics vs. devices) | **Describe the patient’s condition (noting why it is life-threatening/serious)**:      |
| [ ]  2. **No generally acceptable alternative** for treating the patient is available | **Explain why available alternatives are not acceptable** (*e.g., standard therapies have been exhausted; patient does not qualify for research study; research study is not approved at SCH*):      **Explain** **the proposed therapy** (*also* *attach any available materials, protocols, investigator’s brochures provided from the manufacturer*):       |
| [ ]  3. Patient’s condition **requires** **immediate** **treatment**, such that there is not sufficient time to obtain IRB review and approval at a convened meeting.  | **Explain timing considerations**:  |
| [ ]  4. Depending on whether the test article is a drug/biologic or device, the treating physician has made the **additional determinations** specified in the Investigator Manual (HRP-103).  | **For Drugs/Biologics,** determine that the **probable risk** to the person from the investigational test article is not greater than the probable risk from the disease or condition. See Policy 29 for the additional determinations to be made by FDA. |
| **For Devices,** assess the **potential for benefit** from the use of the unapproved device, and to have substantial reason to believe that benefits will exist.  |

**🡪 (1) Email:** After completing parts A & B above, **email this form** to the IRB Chair or designee as directed in HRP-103.

**🡪 (2) Follow-up by Phone:** Next, **call the paging operator** at **206-987-2131** or call the designee at the number listed in HRP-103 and request the IRB Chair or designee to discuss the emergency use criteria. If you are unable to reach any of the IRB representatives listed in HRP-103 before you must use the investigational test article, you may continue with the emergency use process.

**🡪 (3)** IRB Chair or designee sends **confirmation email** to both treating physician and IRB@seattlechildrens.org.

**While seeking IRB concurrence, you may simultaneously work through the other steps in the process, per HRP-103.**

**🡪** Contact the **manufacturer** of the investigational agent about their willingness to make the test article available to your patient.

**🡪** Refer toHRP-103 for information about the necessary approvals from the **sponsor** and/or **FDA** for the emergency use.

**C. Test Article Information**

|  |  |
| --- | --- |
| Name of Test Article:       | Name of Manufacturer:       |
| Who holds the IND (*for drugs/biologics*) or IDE (*for devices*)? [ ]  Treating Physician [ ]  Manufacturer/Sponsor |
| For Drug or Biologic, include emergency **IND#** (*from FDA*):      | For Device, include applicable **IDE#** (*usually* *from sponsor*):  |

**D. Patient Protection Measures. Complete as many as possible *before* using the investigational article:**

[ ]  Written informed consent from patient or their legally authorized representative. See Emergency Use Consent Form Template

***OR***

[ ]  Concurrence of the IRB Chair or designee, confirmed by email

[ ]  *DEVICES ONLY*: independent assessment from uninvolved physician that emergency use criteria are satisfied.

[ ]  Written informed consent NOT obtained 🡪 ***Before*** using the test article, ***determine*** and, if possible, ***document*** (in writing/email) that criteria for **waiving emergency use consent** (see below) are met, in the opinion of:

 [ ]  Physician treating the patient with the test article; ***and***

 [ ]  Physician not participating in the emergency use (independent/uninvolved physician)

🡪 If ***no time*** to get an independent determination from a second physician, the treating physician should ***determine*** that the criteria for waiving emergency use consent are met and proceed with the emergency use. Treating physician should have his/her determination ***evaluated in writing*** by an independent/uninvolved physician ***within 5 working days*** after the use.

**E. Follow-up Report.**

This completed form must be submitted to IRB@seattlechildrens.org within **5 working days after the initiation** of the investigational article.See HRP-103 for information about follow-up reporting to **FDA** and/or **sponsor**.

|  |  |
| --- | --- |
| **Date of emergency use:**       | **Date this follow-up report submitted to IRB:**       |
| Provide patient outcome information **as of the date when this report is submitted** to the IRB. Include any adverse effects. | **Patient’s current condition**:       |
| [ ]  Attached copy of the **signed** emergency use consent form  | **OR** | [ ]  Written informed consent could not be obtained 🡪 See waiver criteria: **Submit** written documentation from the **treating** physician and a **second** independent/uninvolved physician that the emergency situation fulfills the following criteria: 1) The patient was confronted by a life-threatening situation that necessitated the use of the test article; 2) Informed consent could not be obtained because of an inability to communicate with or obtain legally effective consent from the patient; (3) There was insufficient time to obtain consent from the patient’s legally authorized representative; **and** (4) No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patient’s life.  |
| [ ]  Attached email confirmation of IRB concurrence (Chair or designee) | **OR** | [ ]  It was not possible to obtain prior IRB concurrence; please **explain**:  |
| [ ]  For Drugs/Biologics, attached written communication from the FDA documenting the emergency IND#  | **OR** | [ ]  For Devices, obtained prior authorization from IDE sponsor. If sponsor authorization not obtained, **explain**:  |
| [ ]  No additional uses of the investigational agent are anticipated | **OR** | [ ]  Additional uses of the investigational agent are anticipated. **Explain** whether there is a research study available that could be opened at Seattle Children’s:  |
| [ ]  DEVICES only: attached second opinion of an uninvolved physician that the patient meets the ***criteria for emergency use*** (part B above) | **OR** | [ ]  DEVICES only: Second opinion that patient met criteria for emergency use was not obtained prior to the emergency use; please **explain** why it was not possible to obtain a second opinion:  |

**F. Signatures and Approvals**

Physician Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

(Optional Signature if submitted from physician’s e-mail account.)

|  |
| --- |
| **IRB Review of Follow-Up Emergency Use Report** |
| IRB Chairperson Signature:  | Date Noted:       |

**Other Help:**

**Click Library:**

* HRP-023 SOP: All Emergency Use and Compassionate Use (Device Only) Review
* HRP-027 SOP: All Emergency Use and Compassionate Use (Device Only) Post-Review
* HRP-103 Investigator Manual Appendix A-3
* HRP-322 WORKSHEET: Emergency Use