| University of Washington Human Subjects Division  UW  and HSD logo | **APPLICATION Notification of** **Emergency Use, Device** |
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PURPOSE

This form is used by physicians to: **(1)** determine and document whether the circumstances in which they hope to make emergency clinical use of an investigational device meets the FDA requirements for emergency use; **(2)** guide them through the procedures required by the FDA and the UW for emergency use; **and** **(3)** notify the IRB of the emergency use within 5 business days after the use.

*If you have never used a device in this fashion, you are strongly encouraged to speak with an experienced individual in your department or division as soon as possible.*

INSTRUCTIONS

* **Physician follows steps 1-9 outlined below.** Many of the steps can be done concurrently.
* **Physician follows step 10 to notify the FDA of the emergency use.**
* **Physician fills out the IRB notification form in step 11 and submits it to HSD via:** **hsdreprt@uw.edu****.** Completion of the form is not required until after the emergency use has occurred, but the form and all other required reporting must be completed within 5 business days after the device was used. The form should *not* be submitted via *Zipline*, the web-based application system.
* **HSD staff and the IRB Chair complete the IRB assessment described in step 12.**
* **HSD considers each of the hospital facilities** that are part of UW Medicine or the Cancer Consortium to be separate institutions for emergency use of a device (i.e., UWMC, Harborview, Fred Hutch, Northwest Hospital).
* **Residents, fellows, and trainees** may use an investigational device for emergency clinical care only with the advance knowledge of a service chief or similar individual per UWMC or HMC policy.
* **Outcome information for an emergency use is not considered to be research data** and may not be used, presented, or published as research.
* **Consider the probability of possible future use of the investigational device at UWMC or Harborview.** If it is likely, you should initiate efforts to obtain IRB approval and FDA permission for those future uses under an alternative expanded access mechanism (review [website](https://www.washington.edu/research/hsd/guidance/expanded-access/)). These require a full IRB application.

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STEP 1 – Evaluate whether the use meets the FDA criteria for emergency use.

**All of the criteria below must be met.** If the situation does not meet these criteria, use the [**APPLICATION Notification of Compassionate Use, Device**](https://www.washington.edu/research/forms-and-templates/app-compassionate-device/).

1. **The patient is confronted by a** **life-threatening or serious disease or condition requiring immediate use of the device.**
	* + *Life-threatening* means diseases or conditions where: **(1)** the likelihood of death is high unless the course of the disease is interrupted; or **(2)** there is a potentially fatal outcome. The condition need not be immediately life-threatening or to immediately result in death. Rather, the recipients must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible. For the purposes of emergency use, “life-threatening” also includes diseases and conditions that are serious (see definition below).
	* *Serious disease or condition* means a disease or condition involving risk of serious irreversible morbidity, such as sight-threatening or limb-threatening conditions, paralysis, stroke.
2. **There is no generally accepted alternative for treating the patient.**
3. **The physician wants to use the device for a purpose or population not approved under an existing IDE** (Investigational Device Exemption approval from the FDA)**.**
4. **There is no time to use existing procedures to obtain FDA approval of an IDE application.**
5. **There is not sufficient time to obtain IRB review and approval of the use.** [21 CFR 56.104(c)]
	* *Not sufficient time* is not defined by the FDA. HSD defines it as seven (7) business days: two working days for the physician to prepare and submit an IRB application, followed by five (5) working days required for a full IRB committee to review the application.

STEP 2 – Obtain authorization from the manufacturer or holder of the IDE (if there is one).

**You must obtain authorization to use the device from the manufacturer.** The manufacturer is also called the sponsor and typically already has an Investigational Device Exemption (IDE) from the FDA for the device.

* Ask the manufacturer for permission to use the device under the emergency use mechanism.
* If the device is not already physically available at the UW, arrange for shipping of the device.
* If the manufacturer (or other source) requires a letter from the IRB before considering your request or shipping the item, contact the Human Subjects Division at hsdreprt@uw.edu.
* If the manufacturer disagrees with the use, you cannot use the device even if it is physically available at the UW.

STEP 3 – Institutional Clearance – coordinate with UW device distribution oversight.

**Contact the appropriate individuals who manage distribution of investigational devices in your department or division** (e.g., Cardiology, Radiology, Surgical Services)*as soon as possible* to inform them of the planned use and (if applicable) shipment of the device. Provide the following information:

* Name of the device
* The source from which you are obtaining it (e.g., “off the shelf” at UW or from the manufacturer)
* Estimated date and time of use

**You must comply with the UW Medicine policies and procedures about the receipt, dispensing, and use of devices.** This includes obtaining sign-off from the appropriate Executive Director (or designee).

STEP 4 – Institutional Clearance: determine the financial arrangements.

For emergency use at UWMC or HMC, contact the UW Medicine Financial Access Clearance Team (FACT)atfact-compassionateuse@uw.edu to determine who will be responsible for paying for the device and any associated procedures, monitoring, and follow-up (including after the device has been used).

STEP 5 – Institutional Clearance: independent concurrence for use.

**UW Medicine requires you to obtain permission from the appropriate Medical Director (or designee) for the emergency use.** HSD believes that this step also addresses the FDA’s recommendation for an independent assessment from an uninvolved physician.

Follow UW Medicine policy for this concurrence process: The Medical Director (or designee) reviews the patient’s record and writes a statement in the medical record or provides other documentation.

STEP 6 – Institutional Clearance: Billing Compliance

You are required to submit your expanded access use via the central intake form for relevant institutional review: <https://redcap.link/studyintake>

STEP 7 – Contact OSP about Expanded Access Agreements

For expanded access use at a UW Medicine-managed facility (including Harborview Medical Center), Fred Hutch, or where expanded access is occurring under an IDE associated with an existing award under the UW Office of Sponsored Programs (OSP), an Expanded Access Agreement may be required. Please review and follow the instructions [here](https://www.washington.edu/research/myresearch-lifecycle/setup/sponsor-requirements/clinical-research/) under the *Compassionate Use or Single Patient Emergency Enrollment* section. Contact osp@uw.edu with any questions.

STEP 8 – Informed consent.

**The FDA’s informed consent requirements for emergency use are described below.** The consent form is not the same as for a standard clinical consent. The FDA requires the consent process to include all the standard elements of a *research* consent. The UW [**TEMPLATE Consent Form, Emergency or Compassionate Use**](https://www.washington.edu/research/forms-and-templates/template-consent-form-emergency-or-compassionate-use/) meets this requirement and must be used. If you will be able to obtain consent, begin the consent process as soon as possible by discussing the situation with the patient and/or the patient’s legally authorized representative even if you don’t yet have a consent form ready.

When administering an emergency use device to a patient with limited English proficiency, it is preferred that the consent form be translated into the patient’s primary language. If there is insufficient time and opportunity to obtain a written translation, the physician should: **(1)** create an English consent form using the [**TEMPLATE Consent Form, Emergency or Compassionate Use**](https://www.washington.edu/research/forms-and-templates/template-consent-form-emergency-or-compassionate-use/); **(2)** use a medical interpreter to verbally review the consent form with the patient; **and** **(3)** have an impartial third party witness the consent process and sign the consent form.

**Options for consent, in order of FDA preference:**

1. **Whenever possible,** **obtain consent** from the patient or the patient’s legally authorized representative (LAR) using the [**TEMPLATE Consent Form, Emergency or Compassionate Use**](https://www.washington.edu/research/forms-and-templates/template-consent-form-emergency-or-compassionate-use/). Place a signed copy of the consent form in the patient’s medical record and retain an unsigned copy to send to the IRB after the emergency use. You may choose to obtain a UW Medicine clinical consent *in addition* to the emergency or compassionate use consent.
2. **If it is not possible to obtain consent**, the emergency use may still proceed if the treating physician and an independent physician (Medical Director or designee) agree that four specific conditions apply (see below). When using this option, the independent physician must sign the IRB Notification form, or you may attach an email attestation from the independent physician stating that all four conditions were met.
3. **If immediate use of the device is, in the treating physician’s opinion, required to preserve the life of the subject** and time is not sufficient to obtain the concurrence of an independent physician (Medical Director or designee) in advance as described in point 2 above, the treating physician may proceed if all four of the conditions described below are met. Within 5 business days after the use, the treating physician must obtain an independent physician’s assessment as to whether the four conditions were met. When using this option, the independent physician must sign the IRB Notification form, or you may attach an email attestation from the independent physician stating that all four conditions were met.

**Four conditions that must be in place for proceeding with the emergency use without obtaining patient or LAR consent.** [21 CFR 50.23(a)]

1. The patient is confronted by a life-threatening situation necessitating the use of the investigational device.
2. Informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient.
3. Time is insufficient to obtain consent from the patient’s legally authorized representative.
4. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

STEP 9 – Proceed with the emergency use.

**Once steps 1-8 have been completed, the physician may proceed with the emergency use.**

STEP 10 – Notification to the FDA.

**The FDA requires notification when the emergency use has been completed.**

**Who reports:**

* If the manufacturer holds an IDE for the device, provide the report to the manufacturer who will then report to the FDA.
* Otherwise, the treating physician sends the report [directly to the FDA](https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices#emergency):

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

**Report contents:**

* A summary of the conditions constituting the emergency
* Patient outcome and results, including any adverse effects
* Patient protection measures that were followed, which might include:
	+ Obtaining informed consent from the patient or a legal representative
	+ Clearance by any UW device distribution oversight office/individual
	+ Authorization from the manufacturer
	+ An independent assessment from a physician (Medical Director or designee) who is not conducting any research using the device

STEP 11 – IRB Notification Form

**Notifying the IRB is an FDA requirement. This application should be submitted by the treating physician to** **hsdreprt@uw.edu** **within 5 business days after the emergency use. If a letter was issued by HSD prior to the manufacturer considering your request or shipping the item, include a copy of the letter with your application.**

**Type your answers into the form below.**

**11.1. Treating physician’s name (first, last).**

|  |
| --- |
| Click or tap here to enter text. |

**11.2. UW Department or Division.**

|  |
| --- |
| Click or tap here to enter text. |

**11.3. Treating physician contact information.**

|  |  |
| --- | --- |
|  **Phone:** | Click or tap here to enter text. |
|  **Email:** | Click or tap here to enter text. |

**11.4. If you are a resident, fellow, or trainee, provide the name of your Service Chief (or other appropriate individual).**

|  |
| --- |
| Click or tap here to enter text. |

**11.5. Investigational device information.**

|  |  |
| --- | --- |
|  **Name of the device:** |  |
|  **IDE #:** | Click or tap here to enter text. |
|  **Manufacturer:** | Click or tap here to enter text. |

**11.6. Use of device.**

|  |  |
| --- | --- |
| **Facility in which the** **device was used:** | Click or tap here to enter text. |
|  **Date and time of use:** | Click or tap here to enter text. |
|  **Patient age:** | Click or tap here to enter text. |

**The following questions may be answered here or by attaching the report that was provided to the FDA and/or the manufacturer.**

|  |  |
| --- | --- |
|  **Condition for which** **the device was used:** | Click or tap here to enter text. |
| **Current patient status/****result of use:** | Click or tap here to enter text. |

**11.7. Was informed consent obtained from the patient or the patient’s legal representative?**

[ ]  **Yes →** And I will include with my email submission an unsigned copy of the consent form that was used.

[ ]  **No →** Because it was not possible to obtain consent and, *prior to the emergency use*, I (treating physician) **and** an independent physician determined that the [four conditions for not obtaining consent](#NoConsent) were met. The independent physician has signed this notification form, or I will include with my application materials an email from the independent physician stating that they determined those four conditions were met for this emergency use.

[ ]  **No →** Because I (treating physician) determined that immediate use of the device was required to preserve the life of the patient and I did not have time to obtain concurrence from an independent physician. *After the emergency use* I obtained concurrence from an independent physician that the [four conditions for not obtaining consent](#NoConsent) were met. The independent physician has signed this notification form, or I will include with my application materials an email from the independent physician stating that they determined those four conditions were met for this emergency use.

**11.8. Signatures**

**Treating physician.** By my signature, I certify that all of the requirements for emergency use were met in this situation.

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Printed name Signature Date

**Assessment of independent physician (Medical Director or designee).** By my signature, I certify that all [four of the conditions listed in Step 6](#Conditions) of this application form are met in this emergency use situation.

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Printed name Signature Date

12 IRB Assessment [To be completed by HSD Regulatory Affairs (RA) staff and IRB Chair]

**12.1 HSD RA Staff Instructions**

**12.1.a** Verify the submission is complete.A completed submission includes:

* A completed IRB Notification form (above), including all required signatures (or attached email attestation)
* If consent was obtained, an unsigned copy of the consent form that was used to treat the patient which should have been adapted from [**TEMPLATE Consent Form, Emergency or Compassionate Use**](https://www.washington.edu/research/forms-and-templates/template-consent-form-emergency-or-compassionate-use/)
* If consent was not obtained, verify there is a signature (or email attestation) from an independent physician certifying that the conditions were met for not obtaining consent

**12.1.b** Email the complete notification form and supporting materials to the IRB Chair.

**12.1.c** Once the Chair evaluation is complete, email the treating physician to inform them of the outcome.

**12.1.d** Use the **INSTRUCTIONS Zipline for Staff** *Submit RNI for a Single Patient Expanded Access Steps* to enter the notification into *Zipline*. Submit the RNI Pre-Review and RNI Data Entry steps according to **INSTRUCTIONS Zipline for Staff.** There is no need to make any assessments or determinations related to Expanded Access RNI.

**12.2 IRB Chair Instructions**

**12.2.a** Evaluate the notification materials according to the FDA criteria described in this form.

**12.2.b** Contact the treating physician, or ask HSD staff to contact them, about any issues or concerns.

**12.2.c** Email the HSD staff person to confirm that you have reviewed the notification and, in your opinion, either: **(1)** the emergency use *met* the FDA requirements; or **(2)** the emergency use *did not meet* the FDA requirements. This decision will be documented in Zipline and communicated with the treating physician.