| University of Washington Human Subjects Division  UW  and HSD logo | **APPLICATION Single Patient Non-Emergency**  **Expanded Access Use, Drug or Biologic**  **CHAIR CONCURRENCE** |
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The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email** [**hsdreprt@uw.edu**](mailto:hsdreprt@uw.edu) **for assistance.**

PURPOSE

**THIS FORM IS ONLY USED FOR NON-EMERGENCY SINGLE PATIENT USES OF A DRUG or BIOLOGIC in which the treatment is not expected to exceed 1 year.**

**If this is an emergency, use** [**APPLICATION Notification of Emergency Use, Drug or Biologic**](https://www.washington.edu/research/forms-and-templates/app-emergency-drug/)**.**

**If you have NOT requested a waiver from the requirement for full IRB review and approval on Form FDA 3926 (field 10.b) or expect the treatment to last longer than a year, do not use this form.** [**A full IRB application is required**](https://www.washington.edu/research/forms-and-templates/zipline-application-irb-protocol/)**.**

This form is used by physicians to: **(1)** determine and document whether the circumstances in which they hope to use an investigational drug or biologic for clinical treatment of a single patient meet the FDA requirements for expanded access; **(2)** guide them through the procedures required by the FDA and the UW, and Fred Hutchinson Cancer Center (Fred Hutch) if applicable; **and** **(3)** notify the UW IRB of the proposed single patience expanded access (non-emergency) use for chair concurrence **prior** to use.

*If you have never used a drug or biologic in this fashion, you are strongly encouraged to speak with someone in one of the UW Investigational Drug Services (IDS) as soon as possible. Review* [***Step 3***](#Step3) *below for IDS contact information.*

INSTRUCTIONS

* **NOTE –** Some requirements may differ depending on whether UW Medical Center (UWMC), Harborview Medical Center (HMC), or Fred Hutchinson Cancer Center (Fred Hutch) is administering the investigational drug or biologic. These differences are highlighted throughout the form.
* **Physician follows steps 1-10 outlined below.** This form, and all required attachments **(step 10)** must be submitted to **HSD via:** [**hsdreprt@uw.edu**](mailto:hsdreprt@uw.edu). Many of the steps can be done concurrently. Chair concurrence must be obtained **before** starting the treatment with the investigational drug or biologic. 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 11.**
* **HSD considers each of the hospital facilities** that are part of UW Medicine or the Cancer Consortium to be separate institutions for non-emergency expanded access use of a drug or biologic (i.e., UWMC, Harborview, Fred Hutch, Northwest Hospital).
* **Outcome information for a single patient 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 drug or biologic at UWMC, Harborview, or Fred Hutch.** 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 Single Patient Non Emergency Expanded Access use

**All of the criteria listed below must be met.** If the situation does not meet these criteria and the use is planned at UWMC or HMC, contact the Human Subjects Division (HSD) for advice at [hsdreprt@uw.edu](mailto:hsdreprt@uw.edu). For use at Fred Hutch, also contact Clinical Research Support (CRS) Regulatory Affairs at [RegulatoryAffairs@fredhutch.org](mailto:RegulatoryAffairs@fredhutch.org).

1. **The patient has a** **serious or immediately life-threatening disease or condition**. [21 CFR 312.305(a)(1)]
   * + *Immediately life-threatening* means a stage of disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment. [21 CFR 312.300(b)]
   * *Serious disease or condition* means a disease or condition associated with morbidity that has a substantial impact on day-to-day functioning. Short-lived and self-limited mobility will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgement, based on its impact on such factors as survival, day-to-day function, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. [21 CFR 312.300(b)]
2. **There is no comparable or satisfactory alternative therapy.** [21 CFR 312.305(a)(1)]
3. **The potential benefit justifies the potential risk of the use, and those potential risks are not unreasonable in the context of the disease or condition.** [21 CFR 312.305(a)(2)]
4. **The probable risk to the patient from the investigational item is not greater than the probable risk from the disease or the condition.** [21 CFR 312.310(a)(1)]
5. **The use will not interfere with the initiation, conduct, or completion of any clinical investigations of the item that could support marketing approval of expanded access to the item or otherwise compromise the potential development of expanded access use of the item.** [21 CFR 312.305(a)(3)]
6. **The use of the drug or biologic is not already available to the physician through an ongoing clinical investigation at the UW.**

STEP 2 – Obtain authorization from the manufacturer and the FDA

**Contact the manufacturer** (or other source of the item) to determine whether the investigational item can be made available for use.

* Ask the manufacturer for permission to use the drug or biologic under the expanded access mechanism.
* Ask the manufacturer whether they have an existing IND (Investigational New Drug application) that they will allow to be amended for this use.
  + **If yes**, ask whether: **(1)** they are willing to submit the amendment to the FDA; **or (2)** they want you (the treating physician) to prepare and submit the amendment to the FDA. If they want you to submit the amendment, ask them for permission to refer to their existing IND documents.
  + **If no**, you will need to submit an application to the FDA for an IND.
    - Ask the manufacturer for permission to refer to their manufacturer’s IND and supporting documents.
    - FDA instructions for applying for an IND can be found at [this link](https://www.fda.gov/news-events/expanded-access/expanded-access-information-physicians).
* You may need to arrange for shipping of the drug or biologic to UWMC, HMC, or Fred Hutch Investigational Drug Services (IDS) as described in [**Step 3**](#Step3), below. If the manufacturer requires a letter from the IRB before considering your request or shipping the item, contact the Human Subjects Division at [hsdreprt@uw.edu](mailto:hsdreprt@uw.edu).

**FDA authorization must be obtained before the use can occur. Treatment with the drug may proceed 30 days after FDA receives the IND submission or upon notification of the physician by FDA, whichever comes first.**

**Provide a copy of FDA permission, either a copy of the FDA’s permission or documentation of the date of submission to FDA that would indicate 30 days have passed, as part of your submission to the IRB.**

Instructions for physicians on how to submit to the FDA for permission are found here:

[**https://www.fda.gov/news-events/expanded-access/expanded-access-how-submit-request-forms**](https://www.fda.gov/news-events/expanded-access/expanded-access-how-submit-request-forms)

For single patient non-emergency expanded access use at Fred Hutch, the treating physician should work with CRS Regulatory Affairs to contact the FDA ([RegulatoryAffairs@fredhutch.org](mailto:RegulatoryAffairs@fredhutch.org)).

STEP 3 – Coordinate with Investigational Drug Services (IDS)

**Contact the applicable IDS for where the drug is planned to be used (UW, Harborview, Fred Hutch) *as soon as possible* to inform them of the planned use and shipment of the drug or biologic.** Do not wait until you have obtained authorization from the FDA and/or the manufacturer. IDS is a valuable source of guidance and assistance for expanded access situations. You must comply with IDS policies and procedures about the receipt, storage, and dispensing of the item.

* **UWMC IDS:** (206) 598-6054, [uwmcids@uw.edu](mailto:uwmcids@uw.edu)
* **HMC IDS:** (206) 744-5448, [hmcids@uw.edu](mailto:hmcids@uw.edu)
* **Fred Hutch IDS:** (206) 606-2207, [ids.clinical@fredhutch.org](mailto:ids.clinical@fredhutch.org)
* **Fred Hutch Cellular Therapy Laboratory:** (206) 606-1200, [ctlsupervisor@fredhutch.org](mailto:ctlsupervisor@fredhutch.org) and [ctlcto@fredhutch.org](mailto:ctlcto@fredhutch.org)

**Provide the appropriate group above with the following information.**

* Name of the drug or biologic
* The source from which you are obtaining it (e.g., the drug company’s name)
* Any information regarding administration, preparation instructions, and dispensing instructions (dose, route, frequency, etc.). For example, the pharmacist must be able to verify that the written order is correct and that no transcription errors occurred (e.g., 1mg vs. 1gm) before the drug can be released from the pharmacy.
* Estimated date and time of use
* For cell products, due to the complexity of product preparation, as much lead time as possible is required to assess feasibility.

STEP 4 – Institutional Clearance: determine the financial arrangements

For **single patient non-emergency use** at UWMC or HMC, contact the UW Medicine Financial Access Clearance Team (FACT)at[fact-compassionateuse@uw.edu](mailto:fact-compassionateuse@uw.edu) to determine who will be responsible for paying for the drug or biologic and any associated procedures, monitoring, and follow-up (including after the drug or biologic has been used).

For **single patient non-emergency use** at Fred Hutch, inform [researchrc@fredhutch.org](mailto:researchrc@fredhutch.org), providing the patient name, MRN, and proposed date(s) of treatment. Also send them the FDA permission letter when it becomes available.

STEP 5 – Institutional Clearance: independent concurrence for use

**UWMC and HMC** require that you obtain permission from the appropriate Chief Medical Officer (CMO) (or designee) for the single patient non-emergency expanded access use. **For use at Fred Hutch**, obtain permission from the Fred Hutch Chief Medical Officer (or designee).

To meet this requirement, the Chief Medical Officer (CMO) (or designee) reviews the patient’s record and writes a statement in the medical record or provides other documentation.

HSD believes that this step addresses the FDA’s recommendation for an independent assessment from an uninvolved physician and a review of key details of the patient’s history such as Information regarding a patient’s relevant clinical characteristics (such as comorbid conditions and concomitant medications) that is necessary to assess the potential for

increased risks of the drug or biologic.

You will receive an email with the Chief Medical Officer’s approval. **Provide a copy of this email with your submission to HSD**

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**](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 IND 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](mailto:osp@uw.edu) with any questions.

STEP 8– Informed consent

**The FDA requires the consent process** for single patient non-emergency use 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 should be used for UWMC, HMC, and Fred Hutch.

When administering an expanded access use drug or biologic to a patient with a non-English language preference, the consent form should be translated into the patient’s primary language.

STEP 9- Monitoring Plan

Describe the plan for monitoring adverse events, response to treatment, and changes in clinical status, as well as proposed modifications to the treatment plan to mitigate risks to the patient if appropriate. This information is required per [FDA guidance](https://www.fda.gov/media/171902/download). If some of this information is included in Form 3926 please reference that here.

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STEP 10 – IRB Notification

**This form, and all required attachments** must be submitted to **HSD via:** [**hsdreprt@uw.edu**](mailto:hsdreprt@uw.edu)**.**

Required attachments:

1. Form FDA 3926
2. A copy of the treating physician’s CV
3. A copy of FDA permission, either a copy of the FDA’s permission or documentation of the date of submission to FDA that would indicate 30 days have passed
4. Documentation of Chief Medical Officer’s independent concurrence for use
5. The Investigator brochure, a reference to existing information, or supporting literature (for risk assessment)
6. A copy of the consent form that will be used to obtain consent.

STEP 11 IRB Assessment [To be completed by HSD Regulatory Affairs (RA) staff and IRB Chair]

**11.1 HSD RA Staff Instructions**

**11.1.a** Verify the submission is complete.A completed submission includes this application and the 5 required attachments (see step 10). The consent form should include all elements outlined in HSD’s [**TEMPLATE Consent Form, Emergency or Compassionate Use**](https://www.washington.edu/research/forms-and-templates/template-consent-form-emergency-or-compassionate-use/). Review the consent form and determine whether any additional information is needed.

**11.1.b** Email the complete application form and supporting materials to the IRB Chair and/or IRB Vice Chair.

**11.1.c** Once the Chair evaluation is complete, email the treating physician to inform them of the outcome and send letter to physician using **TEMPLATE\_SPNEU\_HSD\_Concurrence\_Letter.**

**11.1.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.

**11.2 IRB Chair Instructions**

**11.2.a** Evaluate the application materials according to the FDA criteria described in this form and [FDA guidance](https://www.fda.gov/media/171902/download).

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

**11.2.c** Email the HSD staff person to confirm that you have reviewed this application and either (1) concur or (2) do not concur with the treatment. This decision will be documented in Zipline and communicated with the treating physician.