WAYNE STATE UNIVERSITY

IRB Administration Office
87 E. Canfield, Second Floor
Detroit, MI 48201
(313) 577-1628
irb.wayne.edu

Single Patient Expanded Access Submission Form

This form is to be completed when there is a single patient who would benefit from treatment of a drug or device that has not received FDA approval. See the following policies available on our policy webpage for more information about the regulations and submission and review process.

- WSU IRB Policy 11-01: Research and Expanded Access Involving Drugs
- WSU IRB Policy 11-02: Approved and Unapproved Devices in Research

If the single patient needing treatment meets the criteria for emergency use, complete the Single Time Emergency Use Submission Form. See WSU IRB Policy 11-03: Emergency Single Time Use of a Test Article.

- All IRB submission forms must be the current form date and typed or computer generated. All forms are available on our website.
- Submit with original signatures—no faxed or copied signatures.

IRB Use Only: **IRB Number**_____

Section A: Administrative Information

1.	Principal Investigator (PI) (Treating Physician):		Date:	
	Credentials (e.g., licenses, certifications)			
	Department:		**E-mail:**	
	Division:		Phone:	( )
	Campus Address:		Pager:	
2.	PI Status: (Select all that apply)	☐ Wayne State Faculty ☐ J. D. Dingell VAMC Staff ☐ Undergraduate Student* ☐ DMC Staff ☐ Resident/Fellow/Trainee* ☐ Other*: ____ ☐ Karmanos Staff ☐ Graduate Student*		
3.	Alternate Contact Person	☐ N/A	**E-mail:**	
			Phone:	( )
4.	Form completed by:	Treating Physician ☐	☐Other: Name:	
	Phone: ( )		E-mail:	
5.	Protocol Title:	*Single Patient Expanded Access Use of*	*in a patient with*	
6.	**Other Personnel:**			

For the purposes of Expanded Access, list any other providers who will have direct, significant involvement with the proposed expanded access use including involvement in the consent process, development of reports to the sponsor and/or FDA, or other regulatory matters. Providers who provide ancillary or intermittent care but who do not have significant involvement do not need to be listed.

Name	Credentials (if applicable)	Role/Responsibilities

Section B: Additional Reviews/Approvals

7.	**a.** Has this expanded access use been approved by the clinical department chair?	☐ Yes ☐ No
	b. Is Radiation Safety review required?	☐ Yes ☐ No
	c. Is Radiation Safety review required?	☐ Yes ☐ No
	d. Is Institutional Biosafety Committee (IBC) committee review required?	☐ Yes ☐ No
	e. Is Billing Analysis required?	☐ Yes ☐ No
	For any items with a 'Yes' response above, include documentation of the review/approval with your submission. If the review/approval is pending, provide documentation of such including the anticipated timeline for the reviews to be completed.	

Section C: Information about the Proposed Use

8.	Expanded Access Product Type:
	☐ Drug: Complete section D ☐ Device: Complete section E ☐ Other: Explain . Contact the IRB Office at 313-577-1628 for submission guidance.

Section D: Expanded Access Use of a Drug

1.	Drug Name:	
	Condition that will be treated:	
	IND Holder: ☐ Industry Sponsor, Name: ☐ Principal Investigator on this application	**IND Status:** ☐ Pending ☐ Approved, IND Number:
	For Investigator-held INDs (cases where there is no industry sponsor): a. Has the drug sponsor or manufacturer agreed to make the drug available for the patient? ☐ Yes ☐ No b. Did/Will the application to the FDA include a request for alternative (i.e., Chair review, rather than full committee) IRB review procedures (section 10b on FDA Form 3926 or in a separate request included with an FDA Form 1571)? ☐ Yes ☐ No	
2.	a. **The patient's condition is a:** ☐ Serious disease or condition *(means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity 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 judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.* ☐ Immediately life-threatening disease or condition *(means a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.)*	
	b. Describe the patient's condition. If this information is already provided in an attachment (e.g., the FDA application), there is no need to provide it again, simply note where the information can be found.	

Section D: Expanded Access Use of a Drug

	c. Explain why there are no other satisfactory therapeutic options for the patient, including a description of any alternatives that have been tried or ruled out:
	d. Explain why the probable risks of the proposed use of this drug for this patient are no greater than the probable risks from the disease or condition:
	e. Describe the treatment plan including the timing, dosage, route of administration, setting where the drug will be administered, the planned duration of treatment, any actions that will be taken to minimize the risks associated with the treatment, and any other relevant information:
	f. Explain how the patient will be monitored for safety (e.g., adverse effects, toxicities):
	g. Explain why the patient cannot obtain access to this drug through an existing clinical trial or other mechanism *(e.g., none exists, the patient does not meet eligibility criteria, travel would be prohibitive, etc.)*:
	h. Describe how the drug will be controlled, including the storage location, the procedures for storage, dispensing, and limiting access to ensure that the drug is only used for this patient.

Section E: Expanded Access Use of a Medical Device

1.	a. Device Name:	
	b. Condition that will be treated: *If this is a proposal for compassionate use of a diagnostic, indicate the disease or condition that is being tested for or ruled out*	
	c. Has the device manufacturer agreed to make the device available for the patient for compassionate use? ☐ Yes ☐ No	
	d. Does an IDE exist for the device? ☐ Yes ☐ No	
	If **yes,** provide the following information:	If **no**, provide the following information:
	IDE Number: **IDE Holder:** ☐ Industry Sponsor, Name: ☐ Physician Investigator, Name:	**Who is submitting the compassionate use request to the FDA?** ☐ The PI named on this application ☐ Device Manufacturer, Name:

Section E: Expanded Access Use of a Medical Device

	IDE Supplement Status (for this proposed use): ☐ Pending ☐ Approved *When there is an IDE, the IDE Holder should submit an IDE supplement to the FDA to request approval for the compassionate use.*	**Status of Request:** ☐ Not submitted yet ☐ Submitted, FDA response pending ☐ Submitted, FDA approved ☐ Other, Explain: *When there is no IDE, either the physician or device manufacturer may submit the request for compassionate use to the FDA.*
2.	**The patient's condition is a:** ☐ Serious disease or condition *(means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity 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 judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.)* ☐ Immediately life-threatening disease or condition *(means a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.)*	
3.	Describe the patient's condition. If this information is already provided in an attachment (e.g., the FDA application), there is no need to provide it again, simply note where the information can be found.	
4.	Explain why there are no other satisfactory therapeutic or diagnostic options for the patient, including a description of any alternatives that have been tried or ruled out:	
5.	Explain why the probable risks of the proposed use of this device for this patient are no greater than the probable risks from the disease or condition:	
6.	Describe the treatment plan including the timing, setting, method of device deployment, any actions that will be taken to minimize the risks associated with the treatment, and any other relevant information:	
7.	Explain how the patient will be monitored for safety (e.g., adverse effects):	
8.	Explain why the patient cannot obtain access to this device through an existing clinical trial *(e.g., none exists, the patient does not meet eligibility criteria, the travel would be prohibitive, etc.)*:	
9.	Describe how the device will be controlled, including the storage location, labelling, and limiting access to ensure that the device is only used for this patient.	

Section F: Costs

1.	Is the drug or device being provided free of charge by the manufacturer? ☐ Yes ☐ No
2.	Describe any costs that the patient and/or their insurance may incur for this treatment and whether the insurer, if there is one, has been consulted regarding coverage.

Section G: Informed Consent

1.	Is the patient able to provide informed consent or will consent need to be obtained from a legally authorized representative (LAR), or in the case of a child, from the parent(s) or guardian? ☐ Patient ☐ Parent/Guardian a. Explain whether the child is capable of providing assent and, if not, why? ☐ LAR: a. Briefly explain why the patient cannot provide consent: b. Briefly explain whether the patient is capable of providing assent and, if not, why?	
2.	Who will be responsible for obtaining consent? *Whomever obtains consent must be medically qualified to explain and respond to any questions regarding the proposed treatment and any related procedures, the risks, and the alternatives.*	
3.	Describe the circumstances under which consent will be obtained including where the process will take place and any steps that will be taken to ensure the patient's privacy and to support their understanding:	
4.	Describe any steps that will be taken to ensure that the patient (or LAR or parent) understands that their decision is truly voluntary and that they are not obligated to provide consent:	
5.	Is the patient (or LAR or parent) proficient in English or will translation be needed? If translation is needed, which language?	
6.	If assent will be sought (from a child or adult with impaired decision-making capacity), describe the assent plan and how assent will be documented. *Include drafts of any materials that will be used to support or document the assent process (e.g., script, information sheet, assent form, etc.) with your submission.*	☐ NA
7.	Is the patient (or LAR or parent) proficient in English or will translation be needed? If translation is needed, which language?	☐ Yes ☐ No

Section H: Confidentiality

1.	Briefly describe where information or records about this treatment, other than those in the medical record, (e.g., follow up reports to the FDA, IRB, or sponsor) will be stored and how the records will be secured to protect the patient's confidentiality:	
2.	Will information about this treatment (e.g., adverse effects, lab results, outcome, etc.) or patient specimens be sent to the drug or device manufacturer (or a physician sponsor if the IND or IDE is not held by the manufacturer)?	☐ Yes ☐ No
	If Yes, complete the following: a. Briefly describe the information/specimens the manufacturer/sponsor is requesting:	
	b. Briefly describe how the information/specimens will be securely transmitted or transferred:	
	c. Indicate whether any of the following identifying elements will be included: ☐ Names ☐ All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes ☐ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age ☐ Phone numbers ☐ Email addresses ☐ Social Security numbers ☐ Medical record numbers ☐ Health plan beneficiary numbers ☐ Account numbers ☐ Certificate/license numbers ☐ Vehicle identifiers and serial numbers, including license plate numbers ☐ Device identifiers and serial numbers ☐ Web Universal Resource Locators (URLs) ☐ Internet Protocol (IP) address numbers ☐ Biometric identifiers, including finger and voice prints ☐ Full face photographic images and any comparable images ☐ Any other unique identifying number, characteristic, or code (other than a unique code you may assign to the records to protect the patient's identity) ☐ Derivatives of any of the above (e.g., initials, partial name, partial SSN, etc.)	

Include with this submission (as applicable):

- ☐ Derivatives of any of the above (e.g., initials, partial name, partial SSN, etc.)
- ☐ Materials and any correspondence submitted to and/or received from the FDA
- ☐ Letter of Authorization or similar documentation of approval from manufacturer or sponsor
- ☐ Independent Physician Assessment (Required by FDA for Expanded Access use of a medical Device)
- ☐ Investigators' Brochure (drugs), Instructions for Use (devices), or similar documentation providing information about the drug or device and the known safety information
- ☐ Clinical Protocol or Treatment Plan (The plan should include an appropriate schedule for monitoring the patient, taking into consideration the investigational nature of the drug/device and the specific needs of the patient. If treatment of the patient will deviate from a sponsor-provided protocol, provide an explanation of any such deviations.
- ☐ Draft Informed Consent Form

DEPARTMENT CHAIR/DEAN CERTIFICATION

Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? ☐No ☐Yes*

In signing below, the Department Chairperson or Institute/Center Director certifies that (1) appropriate support will be provided for the administration of unapproved drug or device for treatment purposes, and (2) appropriate scientific and ethical oversight has been and will be provided

Signature of WSU Department Chair/Dean Title Date

INDEPENDENT PHYSICIAN ASSESSMENT CERTIFICATION

Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? ☐No ☐Yes*

In signing below, I certify that I am an independent physician, and upon my assessment, I certify that the use of the unapproved drug/device is the appropriate course of treatment for this patient's disease.

Signature of Independent Physician Title Date

PRINCIPAL INVESTIGATOR (TREATING PHYSICIAN) CERTIFICATION

Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? ☐No ☐Yes*

By signing below, I certify that the information contained in this application and any associated materials is accurate. Any proposed changes to this information will be submitted for IRB review and approval prior to implementation (unless necessary to eliminate an apparent immediate risk of harm, in which case the issue and action taken will be reported to the IRB promptly). I am aware that prior approval from both the FDA and IRB is needed before the expanded access use occurs and will not move forward until both are in place.

Signature of Principal Investigator/Treating Physician Title Date

If yes, there must be a "Financial Conflict of Interest Detailed Disclosure Form" submitted to the Financial Conflict of Interest Committee annually or when changes occur. The form and more information are available at: www. research.wayne.edu/coi. For additional information please contact the Conflict of Interest Coordinator, 5057 Woodward, Suite 6305, Detroit, MI 48202, Fax 313-577-2159, Phone 313-577-9064.