**HRP-503X Protocol Template for**

**Expanded Access Programs (EAPs) and Compassionate Use**

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| *Expanded access refers to the use of an investigational drug or device outside of a clinical trial by patients with serious or life-threatening conditions who do not meet the enrollment criteria for the clinical trial in progress. This type of access may be available, in accordance with United States Food and Drug Administration (FDA) regulations, when it is clear that patients may benefit from the treatment, the therapy can be given safely outside the clinical trial setting, no other alternative therapy is available, and the drug/device developer agrees to provide access to the drug/device. The FDA refers to such a program as an expanded access program (EAP). EAPs can be leveraged in a wide range of therapeutic areas (including HIV/AIDS and other infectious diseases, cancer, rare diseases, and cardiovascular diseases, to name a few).* *(see* <https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/>*)*  |

**Investigational Drug or Device Name:**

*Provide the full protocol title as listed in IRES IRB*

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**Principal Responsible Physician:**

*Name:*

*Department:*

*Telephone:*

*E-mail Address:*

**Version Date:**

*Provide the date of this submission*

1. **YNHH Information**

Please note that if this protocol includes Yale-New Haven Hospital patients, including patients at the Hospital Research Unit, the Principal Physician and any other listed clinicians who are physicians or mid-level practitioners (includes PAs, APRNs, psychologists and speech pathologists) who may have direct patient contact with patients on YNHH premises must have medical staff appointment and appropriate clinical privileges at YNHH. If you are uncertain whether the study personnel meet the criteria, please telephone the Physician Services Department at 203-688-2615. By signing this protocol as a Principal Physician, you attest that you and any co-investigator who may have patient contact has a medical staff appointment and appropriate clinical privileges at YNHH.

Once obtained, the PI is to submit IRB approval to the relevant YNHH Vice President or Service Line director for YNHH review and approval. If the HUD is approved for use at YNHH, an individual shall be designated in the relevant department to control the inventory, dispensation and chain of custody of the device(s). This individual must be notified of any use by the PI, prior to use for a planned procedure and as soon as possible thereafter in the event of an emergency use. Your request must be reviewed and approved in writing by the appropriate YNHH committee before patients/subjects may be scheduled to receive the investigational device or investigational procedure.

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| **If you need help…** |
| Yale University Human Research Protection Program<https://your.yale.edu/research-support/human-research> 25 Science Park 3rd floor150 Munson StreetNew Haven CT, 06520Phone: 203-785-4688Email: hrpp@yale.edu  |  |
| **Instructions for using this protocol template:**1. Use this template for projects requesting the Expanded Access Program/Compassionate Use mechanism to treat a patient or small patient population.
2. Add this completed protocol template to your study in IRES IRB in the “Basic Information” section.
3. This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB.
4. There may be sections in this template that do not apply. If so, provide the response “Not Applicable”.
5. **DO NOT TYPE IN THE GRAY BOXES.** All guidance language appears in *gray boxes* and must be deleted from the final version of the protocol prior to submission.
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# Description of the Investigational Drug or Device

## Drug or Device Manufacturer Information

*Provide the name, address, contact information for the drug or device manufacturer.*

## Generic and Trade Name of the drug or device

*Provide the generic and trade name of the drug or device.*

## FDA IND or IDE number and holder

*Provide the IND or IDE number and the holder.*

## Description of the drug or device

*Describe the drug or device: The condition/disease for which the drug/device is under FDA-approved investigational use, and any other indications approved by the FDA for use of the drug or device. Include information on previous use.*

*Describe the contraindications, warnings, and precautions for the use of the drug or device.*

*List the alternative FDA-approved practices and procedures, if any.*

# Use Request

*Describe the eligibility criteria, usual treatment history for a patient who would qualify for use of the drug or device, the reason use of the drug or device is worth the risk to the patient at this time, and the procedures and methods that the patient(s) will undergo. Indicate if this access is for a single patient, an intermediate size patient population, or widespread treatment use.*

# Consent Process

*Describe the process of clinical consent for the procedure: personnel obtaining consent, assessment of the patient’s capacity to consent, conditions under which consent will be obtained, any steps to minimize undue influence and any steps to enhance the patient’s independent decision-making, such as a waiting period. If non-English-speaking patients are to receive the drug or device, describe provisions in place to assure comprehension. If the patient is a minor, describe how parental or guardian permission will be obtained*

# Unanticipated Problems Involving Risk to Patients or Others

***NOTE****: The following unanticipated problems must be reported to the HIC promptly (at least within 5 days of becoming known to the physician):*

*a. Problems or events that are unexpected (in terms of nature, severity, or frequency) given the treatment procedures and the characteristics of the patient population;*

*b. Problems or events that suggest that the drug or device places the patient at greater risk or harm (including physical, psychological, economic, or social harm) than was previously known or recognized; and*

*c. Problems or events that are related or possibly related to the patient’s receipt of the drug or device.*

*(Describe who will be responsible for monitoring patient safety and reporting unanticipated problems.)*

# Risks and Discomforts

*Describe the potential risks and discomforts to patients and methods of minimizing these risks.*

# Financial Information

*Describe what the patient will be told about the cost of the drug or device and procedures and how insurance/Medicare will handle billing for this drug or device and procedures.*

# Benefits

*Describe the potential benefits to patients.*

# Drug or Device Storage Plan

*Describe how the drug or device will be handled, administered, dispensed, and stored to ensure that it is used only for appropriate patients.*

Upload the following supporting materials with this submission in IRES IRB:

* The drug or device manufacturer’s product labeling, clinical brochure, and/or other pertinent manufacturer informational materials\*
* The FDA letter documenting the IND or IDE number\*
* The patient information booklet from the sponsor\*
* The package insert, supporting literature provided by the sponsor, summary of safety information and probable benefit brochure

***\* These documents are required for review.***