

DUHS IRB Application (Version 1.0)

General Information

***Please enter the full title of your protocol:**

Expanded Access: Individual patient IND for treatment of [insert indication] with [insert investigational drug name].

***Please enter the Short Title you would like to use to reference the study:**

Expanded Access: [Insert Drug Name]
 * This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Add Study Organization(s):

List Study Organizations associated with this protocol:

Primary Dept?	Department Name
<input type="radio"/>	[REDACTED]

Assign key study personnel (KSP) access to the protocol

***Please add a Principal Investigator for the study:**

(Note: Before this study application can be submitted, the PI MUST have completed CITI training)

Jennifer Hamill

3.1 If applicable, please select the Key Study personnel: (Note: Before this study application can be submitted, all Key Personnel MUST have completed CITI training)

**** Denotes roles are not recognized in OnCore. Please select an appropriate role that is recognized in all clinical research applications (iRIS, OnCore, eREG, etc.)***

A) Additional Investigators, Primary Study Coordinator (CRC), and the Primary Regulatory Coordinator (PRC):

B) All Other Key Personnel

***Please add a Study Contact:**

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g., The study contact(s) are typically the Principal Investigator, Study Coordinator, and Regulatory Coordinator.)

Protocol Linking Test

Protocol test

View Details	Protocol Status	RB Number	Short Title	Principal Investigator	Expiration Date
			Protocol Title		

No Protocols are Linked to this Protocol

Oncore

Please select the Library for your Protocol:

This field is used in OnCore. Determines the Reference Lists, Forms, Protocol Annotations, Notifications, and Signoffs available for the protocol. Protocols that require reporting to the NCI (National Cancer Institute), must select the Oncology library.

- Oncology
- Non-Oncology

Protocol Application Type

Select the type of protocol you are creating:

Please see additional criteria and information in the policy titled "Reliance on the IRB of Another Institution, Organization, or an Independent IRB" on the [IRB web site](#).

- Regular Study Application - Most common. The IRB will determine if the study is eligible for expedited review or requires full board review upon submission.
- Application for Exemption from IRB Review - Includes Exempt, Not Human Subject Research, & Not Research.
- External IRB Application - Any study using an external IRB as the IRB-of-Record.
- Trainee Research While Away from Duke - Research conducted by medical students overseen by the Office of Curriculum & other student/trainee research away from Duke.
- Individual Patient Expanded Access, Including Emergency Use - Use of an investigational product under expanded access, including emergency use of an investigational drug or biologic or emergency use of an unapproved device.

Individual Use of a Test Article

Does the patient meet the criteria for individual expanded patient access?

(1) The patient to be treated has a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.

(2) The potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated .

Yes No

Are you using an investigational drug?

Yes No

Are you using an investigational device?

Yes No

Please select one of the following.

- Emergency Use
 Non-Emergency Use

1. **Emergency Use** : Patient has an immediately life-threatening condition that requires treatment within a very limited number of hours or days. Emergency use should be requested when a patient may need to be treated before a written submission can be sent to the FDA to authorize use of the investigational product.

If the product is an investigational drug, the treating physician should communicate the emergency use request to FDA by telephone or other rapid means of communication and wait for FDA authorization of the expanded access use before proceeding. FDA may authorize the expanded access use to begin by telephone. If the product is an investigational device, the treating physician may proceed with the emergency use treatment following as many patient protection procedures as possible. FDA should be notified of the emergency use of the investigational device within 5 working days.

2. **Non-emergency Use**: Patient has a serious or immediately life-threatening condition that requires treatment outside of the criteria defined by emergency use. While there is a 30-day review period before treatment with the investigational product may begin, FDA typically authorizes non-emergency use requests sooner than 30 days. In addition to FDA authorization, prospective IRB chair concurrence is required for non-emergency use requests.

I agree the use of the test article does not involve a systematic investigation designed to develop or contribute to generalizable knowledge.

Yes No

I agree that any information (excluding safety information reported to the FDA and/or provider) obtained from the use of the test article cannot be used for research purposes, such as for assessing the effectiveness of the test article.

Yes No

Provide a brief clinical history of the patient, including age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy, and the reason for the expanded access request, including an explanation of why the patient lacks other therapeutic options.

DO NOT include direct identifiers such as name, SSN, MRN, etc.

Brief clinical history of the patient, including age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy, and the reason for the expanded access request, including an explanation of why the patient lacks other therapeutic options.

Date the test article will be used:

11/10/2020

Describe how you will use the test article:

Attach any FDA and/or IRB correspondence related to this request in the Initial Submission Packet.

Describe how you will use the test article

Describe your plan for monitoring adverse events:

Describe your plan for monitoring adverse events

Consent Process

Attach draft consent forms in the Initial Review Submission Packet.

Consent forms must be MS Word documents and follow the specific format outlined by the IRB. **[Click here](#)** to download a copy of the consent form template.

Note: Please do not edit the section of the footer that contains the Protocol ID, Continuing Review and Reference Date fields. Those fields will be used to stamp the final consent form when it is approved by the IRB. If you want to add an internal version date, please put it in the header.

Who will conduct the consent process with prospective participants?

Give the person's role in this study (PI, Study Coordinator, etc.):

The PI will consent this patient and the PI is the patients clinical treating physician

Who will provide consent or permission?

(Select all that apply):

- Participant
- Parent(s) or Legal Guardian(s)
- Legally Authorized Representative (LAR)

Drugs, Biologics, and Other Substances

Drugs, biologics, or other substances being evaluated as a part of this research study:

Add all drugs, biologics, or other substances being evaluated as a part of this research study for which an IND is provided for the indication used in this study.
Also add any other drugs, biologics or other substances here that are being used as a part of this research study, for which an IND is not provided.

List every other drug, biologic or other substance for which side effects are described in the consent form.

View Details	Drug Name	FDA Approved	A new drug or a new use of approved drug:	IND Number
<input type="checkbox"/>	Drug/Biologic /Substance Aspirin Generic Name: Generic Drug Name: Investigational Drug Name:	No	No	1111111

Drug/Biologic/Substance Generic Name:	Aspirin
Generic Drug Name:	
Investigational Drug Name:	
Drug/Biologic/Substance Source:	Investigators Brochure
Is the drug/substance being provided to the subject free-of-charge?	Yes
Is the Drug FDA Approved?:	No
Is this drug/biologic or other chemical, metabolite, nutritional substance or other substance to be used in this research subject to the provisions of the Controlled Substances Act?	No
Does this Drug have an IND Number?	Yes
IND Number	1111111
IND Holder:	PI holds the IND
IND details:	
If FDA Approved and an IND is not required, Please provide a rationale for exemption:	N/A
Will drug/substance be shipped from Duke to external locations	No
Dose Range:	1 mg
Frequency:	daily
Will this drug, biologic, chemical, metabolite, nutritional substance	No

or other substance be manufactured or compounded at Duke?

Drug Storage Restrictions (including temperature, etc.):

none

As indicated in the Investigator's Brochure or other available documentation, what is the highest FDA Use-in-Pregnancy Rating for drug used for research purposes in this study?:

B

Are you using an investigational pharmacy at Duke?

Please be aware that inpatient administration of an investigational drug requires the use of the Duke IDS or Oncology ICS, as per Department of Pharmacy policy.

Yes No

Has the provider of the test article (drug) granted written approval for its use as described in this "Expanded Access for Individual Patients, including for Emergency Use application?"

Yes No

Attach a copy of the written approval in the Initial Submission Packet.

Application Questions Complete

Please click Save & Continue to proceed to the Initial Submission Packet.

The Initial Submission Packet is a short form filled out after the protocol application has been completed. This is an area to attach protocol-related documents, consent forms, and review the application.