INSTRUCTIONS FOR USE OF SHORT FORM IN OBTAINING INFORMED CONSENT

PURPOSE OF THE INFORMED CONSENT SHORT FORM

This form is an option for obtaining informed consent or parental permission for a patient who is being offered treatment under an expanded access investigational new drug protocol held by the Centers for Disease Control and Prevention (CDC).

The Informed Consent Short Form should be used when the required elements of informed consent are presented orally to a patient or the patient's legally authorized representative (LAR). The short form and applicable written summary are translated into the patient's preferred language. The short form describes the required elements of informed consent and specifies that those elements, as they pertain to the treatment, will be presented orally to the patient/LAR. Details pertaining to the specific treatment are included in the written summary.

Whenever possible, short form and written summary translations that are already approved by the CDC Institutional Review Board (IRB) should be used. The CDC IRB-approved short form(s) should be used as is with no changes, except to specify the following (in English):

1. Title of the Expanded Access Investigational New Drug (IND)
2. Name of Treating Physician and Contact Information
3. Emergency Contact Person/Institution and Contact Information

When a CDC IRB-approved informed consent short form translation is not available in the language needed, the English version of the CDC IRB-approved informed consent short form must be used for translation by a certified interpreter. If a certified interpreter is not available, another adult who is fluent in both English and the language needed may interpret, provided the patient (parent/LAR) is comfortable sharing medical information (i.e., the reason treatment is being offered). If a facility wishes to create a written translation of the short form, the CDC IRB-approved informed consent short form must be translated by a certified translator and the translation must be submitted to and approved by the CDC IRB prior to use.

HOW TO CONSENT WITH A SHORT FORM

The treatment provider presents the consent and written summary information to the patient (parent/LAR), using an interpreter as needed. The patient (parent/LAR) has an opportunity to ask questions. Consent/parental permission is then documented on both the Informed Consent Short Form in the patient's (parent's/LAR's) preferred language and on the written summary.

Responsibilities of the Interpreter

The interpreter must be fluent in both English and the preferred language of the subject (parent/LAR). When the treatment provider presents the consent information to the patient (parent/LAR), the interpreter presents the information in the subject's (parent's/LAR's) preferred language.

Witness to the Short Form Consent Process

Either the interpreter or a second individual (fluent in both languages) can serve as the witness. The witness cannot be otherwise involved in providing the treatment. The witness can be an adult family member, friend, a clinic nurse who is not involved in providing the treatment, or anyone else 18 years or older with whom the patient (parent/LAR) is comfortable sharing medical information (i.e., the reason treatment is being offered).

Attestation to the Short Form Consent Process

With their signatures, the person obtaining consent and witness attest to the following:

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the patient in a language preferred by and understandable to the patient; and
- The patient's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the patient.
- At the conclusion of the consent process, the patient was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the patient's questions) and responded affirmatively.

Patient Copies

The patient (parent/LAR) must be provided copies of both the short form and the written summary.

Title (In English): Use of Tecovirimat (TPOXX) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children

Treating Physician: Name and phone number

In the event of an emergency, you should go to an emergency room or call 911

You (or your child) are being offered a drug called [drug name] to [treat/prevent] [disease/condition/illness]. [Drug name] has not been approved to treat or prevent [disease/condition/illness].

Before you agree, your doctor must tell you about this drug. Your doctor will give you information to help you decide if you want to use this drug or if you do not want to use the drug. Using this drug is your choice. Your doctor will tell you:

- what this drug is normally used for and why they are using this drug to treat [disease/condition/illness]
- that they do not know how well this drug works to treat [disease/condition/illness]
- that they do not know if this drug is safe for you
- that this drug may make you feel sick or feel pain and what to do if this happens
- if this drug might help you
- how they give this drug to you and how long it will take to give you the drug
- if they will have to do any tests before or after they give you this drug
- if there are other drugs or ways to [treat/prevent] [disease/condition/illness]
- if you must pay to use this drug
- what to do if you are hurt or injured by this drug
- what treatment is available if you are hurt or injured by this drug and if you will have to pay for it
- they will not tell anyone you got this drug unless they have to by law
- it is your choice if you want the get this drug or not and you will get the same care either way
- you can stop taking the drug at any time
- your doctor can stop the drug at any time, such as if the drug is hurting you
- you can ask questions and your questions must be answered

If you chose to get this drug, you must sign this form and you must sign another form. You will get a copy of both forms that you signed.

- You can call your doctor at [the phone number] if you have questions about this drug or if you think you have been hurt or injured by this drug.
- You can call the CDC at 1.800.584.8814 or email them at huma@cdc.gov if you have questions about your rights. Tell them you are a patient that got [drug] and how to call you back.

By signing your name below, you agree that you were told orally about all the things above and you choose (choose for your child) to get [drug name]. You will get a copy of this form to keep. You will also get a copy of the information that was given to you about the treatment program.

Signature of patient capable of consent	Date

My signature documents that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the patient or their legally authorized representative and that consent was freely given by the patient or their legally authorized representative.

Signature of witness to consent process	Date