

## Information regarding Monkeypox

### Approved Vaccines

The federal government has allocated a limited number of approved vaccines (e.g., JYNNEOS) to state health departments to make these doses available to protect against monkeypox. The JYNNEOS vaccine is approved for adults and, recently, also for children under an Emergency Use Authorization. As long as these doses are used on-label, no IRB review is required.

### Investigational Drugs: TPOXX (Tecovirimat)

CDC has an approved protocol for use of TPOXX: "Expanded Access IND Protocol: Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children," with IND No. 116,039.

CDC published the following: [Information for Healthcare Providers on Obtaining and Using TPOXX \(Tecovirimat\) for Treatment of Monkeypox](#). Follow the CDC instructions on this page. All required forms are available on the CDC website. These include a required:

- Informed consent form
- Patient Intake Form
- FDA Form 1572
- Clinical Outcome Form

The University and UCHHealth are pursuing a joint IRB reliance agreement for all uses by our institutions.

### Other Investigational Drugs

If other investigational drugs become available for emergency or single-patient use, follow standard guidance below as appropriate:

- [Emergency Use](#)
- [Single Patient INDs](#)

Traditional clinical trials for investigational products need to go through standard review processes.