

**Purpose:** To provide Michigan Medicine physicians and advanced practice providers (APPs) with guidance on the use of investigational drugs and devices for clinical care.

**Scope:** This guidance applies to all Michigan Medicine physicians and APPs.

Michigan Medicine strives to provide the best medical care to patients and recognizes the need for and desire of patients to pursue investigational interventions (e.g., drugs, biologics and devices) when other therapeutic options have been exhausted. Access to investigational interventions can take three forms:

1. **Clinical trials**, for those who meet trial eligibility criteria (“qualify”). This mechanism requires IRB review and approval as this is considered research.
2. **Expanded Access** through the FDA, for those with life-threatening or serious illnesses who do not qualify for clinical trials and have exhausted other available treatment. Expanded Access requests require review and approval by the FDA and the IRB, each of which provides guidance and feedback on safety and informed consent. Expanded Access is not research and is a form of clinical care.
3. **Right to Try**, also for those with life-threatening or serious illnesses who do not qualify for clinical trials and have exhausted other available treatment. These requests only require approval by the manufacturer of the drug. The treating physician is responsible for certifying the patient meets the criteria for treatment and for obtaining informed consent from the patient. Right to Try is not research and is a form of clinical care.

For drugs and devices approved for any indication, the **Innovative Care** guidelines may apply. Innovative Care relates to the use of approved therapies for clinical care in unapproved indications or patient populations. As such, innovative care must be distinguished from research and from clinical care utilizing investigational agents not yet approved by the FDA (Expanded Access and Right-to-Try). The Innovative Care Guidance provides more information to help determine when it is appropriate to proceed with approved treatments for unapproved indications. It is available under Selected UMHS Resources on the Michigan Medicine Clinical Home Page:

<http://www.med.umich.edu/clinical/clinicalresources.htm>.

It is the position of Michigan Medicine that FDA’s Expanded Access process provides critical patient protections in the use of investigational drugs, biologics and devices, and, therefore, Michigan Medicine leadership **discourages** physicians and APPs to access these investigational interventions for their patients through the Right to Try mechanism. Michigan Medicine provides support for FDA and IRB submissions through the Michigan Institute for Clinical and Health Research (MICHR) IND/IDE Investigator Assistance Program (MIAP).

Understanding that there may be unique patient care circumstances in which Right to Try may be an appropriate mechanism for access to investigational care, the treating physician is responsible for the following process. Prior to initiating care under Right to Try, the physician should convene a discussion among his or her peers at a staff meeting or case conference, which may include the division chief, department chair, and/or clinical service chief. The following factors should be considered:

- the risks and benefits of the proposed treatment,
- the applicability of the proposed treatment to the patient's unique circumstance,
- whether an extension of privileges should be requested,
- necessary informed consent elements, and
- whether the proposed treatment should be more appropriately undertaken as a research study or through the Expanded Access mechanism.

The physician will document the outcome of this discussion in the electronic medical record.

All requests for clinical use of investigational drugs, biologics or devices (including Right to Try) within Michigan Medicine must be approved by IRBMED. All uses of investigational drugs or biologics must be reviewed by Research Pharmacy.