https://www.fda.gov/news-events/public-health-focus/expanded-access

Expanded Access

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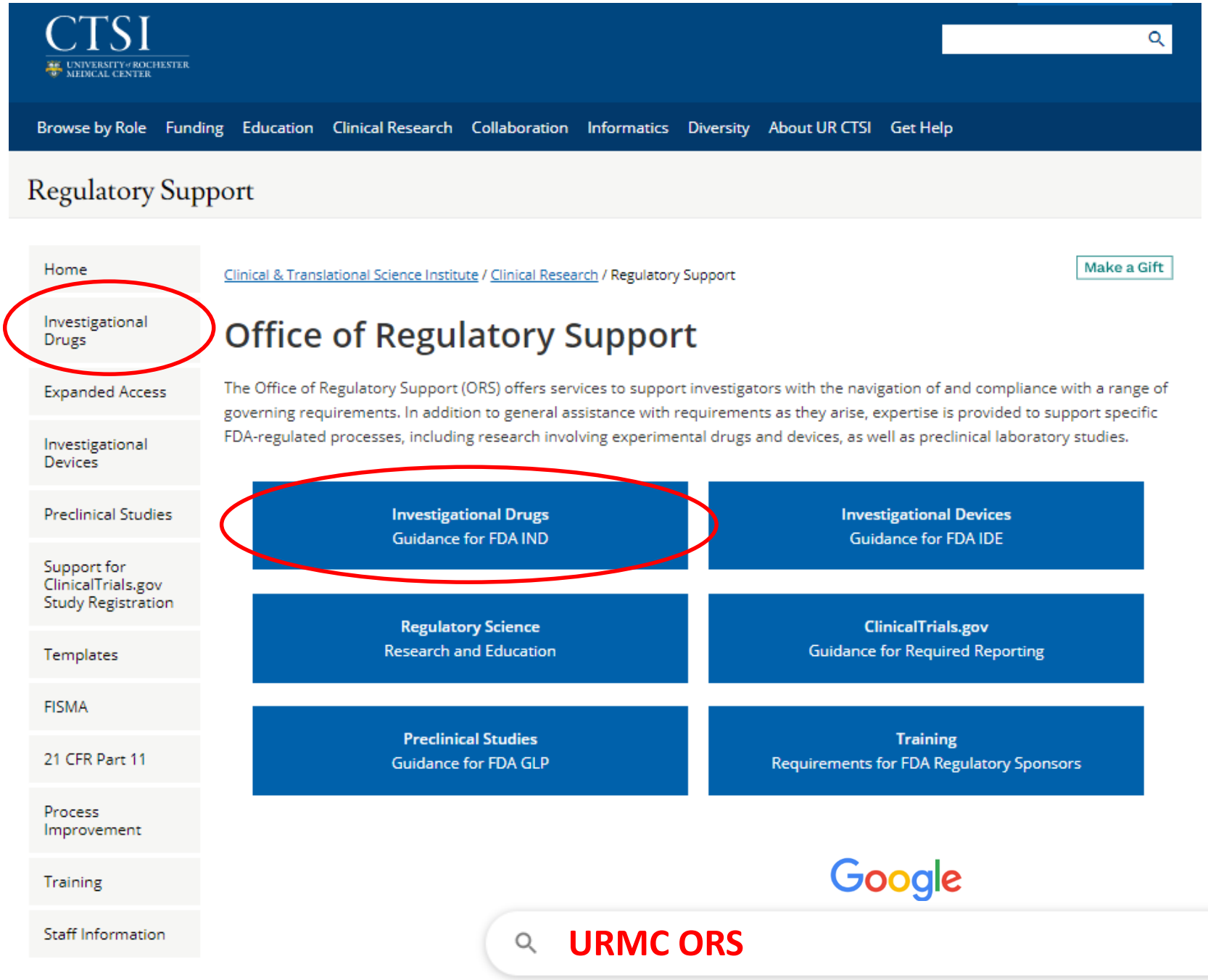
Sometimes called "compassionate use", expanded access is a potential pathway for a patient with an **immediately life-threatening condition or serious disease or condition** to gain access to an **investigational medical product** (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

https://www.urmc.rochester.edu/clinical-translational-science-institute/clinical-research/regulatory-support.aspx



https://www.urmc.rochester.edu/clinical-translational-science-institute/clinical-research/regulatory-support/investigational-drugs.aspx

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Investigational Drugs

New: Expanded Access - The process for requesting use of a non-FDA-approved, investigational drug outside of a clinical trial setting has been formalized at the University of Rochester. This Expanded Access process has a REDCap Application to expedite the coordination of all groups which need to be involved.

The Office of Regulatory Support (ORS) provides a variety of services to support development of Investigational New Drug (IND) application submission, and provides guidance and assistance throughout the life cycle of IND-regulated studies.

An IND Training course, designed to provide local requirements for filing an IND application as the Regulatory Sponsor and to educate on FDA requirements, is offered. Students can access it through Blackboard. Faculty and staff can access it through MyPath. This training will take less than an hour, and is required for any investigator who will be submitting (or who currently holds) an active IND and optional (but strongly recommended) for study coordinators and research staff involved with the submission and maintenance of an IND.

IND applications will be filed with the Center for Drug Evaluation and Research (CDER) if the product is a drug and to the Center for Biologics Evaluation and Research (CBER) if the product is a biologic, vaccine, blood product or a cell-based product.

University of Rochester Faculty and Staff Access to IND training through MyPath.
Rochester student access to IND training through Blackboard.

In both MyPath and Blackboard, use the search bar feature and the keywords, "Investigational New Drug."

Those not affiliated with the University of Rochester can view the IND training through the UR CTSI Portal.

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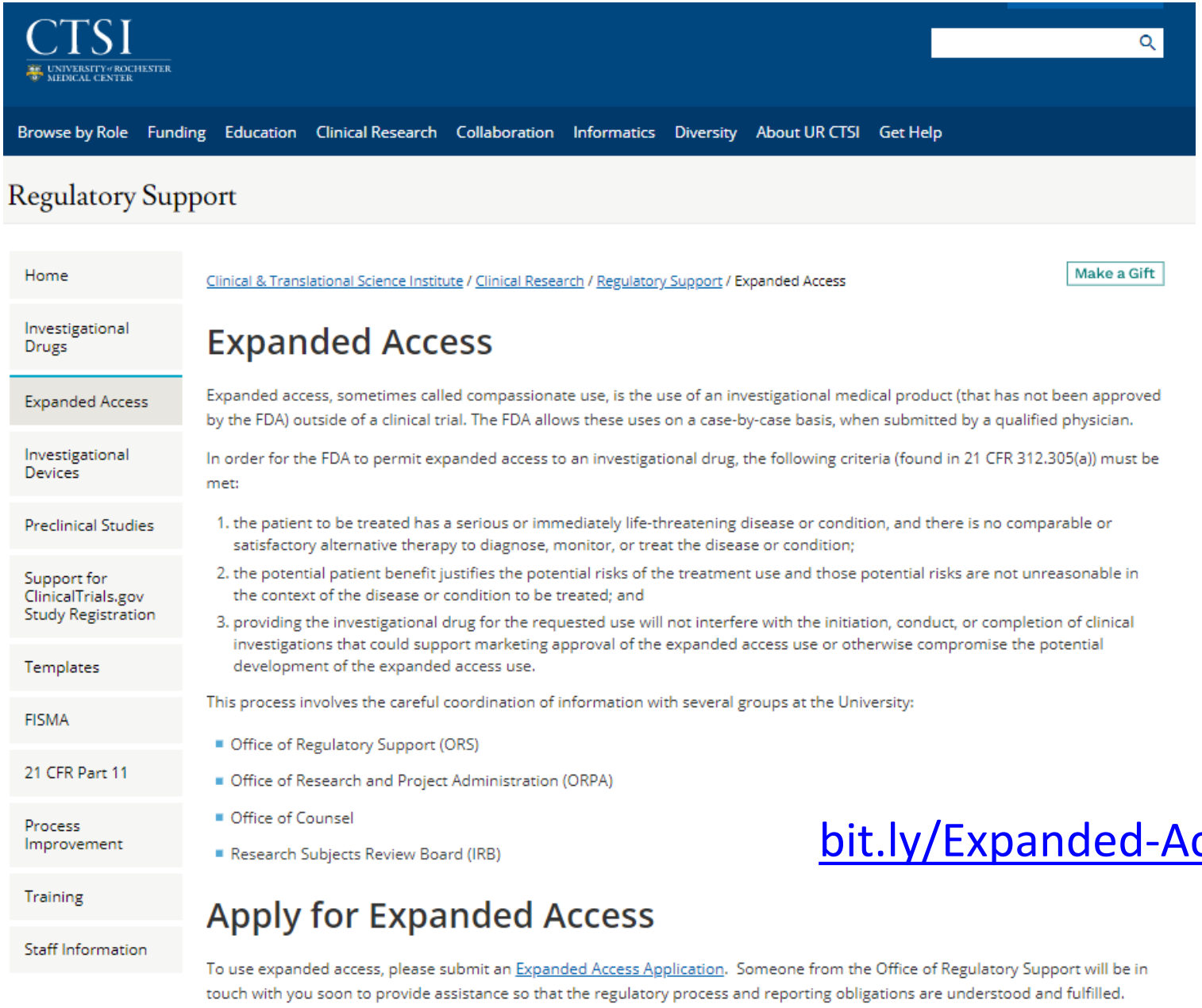


bit.ly/Expanded-Access

https://redcap.urmc.rochester.edu/redcap/surveys/?s=7RCWF4TC3N

FDA Forms! → https://www.fda.gov/about-fda/reports-manuals-forms/forms

FDA Form 1571 Updates

On May 4th, 2018, the FDA updated FDA Form 1571. Information is provided in this document on the three major changes.

- **Commercial IND or Research IND**
- **Combination Products**, and
- **Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)**

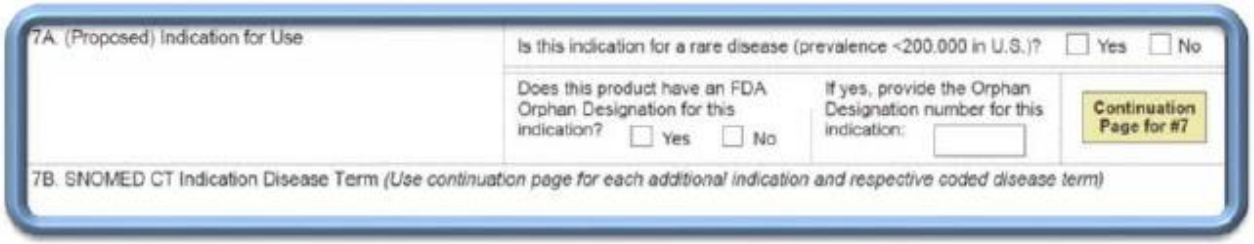
Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)

SNOMED CT is the most comprehensive clinical healthcare terminology in the world supported by National Library of Medicine (NLM), Center for Disease Control (CDC) and Prevention and the Office of National Coordinator (ONC) for Health Information Technology.

SNOMED CT is the required FDA terminology standard for coding study data indications of IND submissions.

See field 7A and 7B on the 1571.

- Field 7 changed to 7A
- Field 7B added to capture the SNOMED CT Indication Disease Term



https://www.urmc.rochester.edu/clinical-translational-science-institute/clinical-research/regulatory-support/training.aspx

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Clinical & Translational Science Institute / Clinical Research / Regulatory Support / Training

Training

FDA Form 1571 has been updated. Use this new form for all future IND submissions to the FDA. Refer to this training document to walk you through the changes.

All University of Rochester investigators are required to complete the IND or IDE training before submitting an IND or IDE application (respectively) to the FDA. Training is optional (but strongly recommended) for members of the study team who will be working on FDA-related aspects of the study.

These online courses are available in three locations: one in Blackboard for University of Rochester students, a separate version in MyPath for University of Rochester staff and faculty and a third version for the scientific public. They are the same course and each team member only needs to complete the version that is appropriate for them.

In both MyPath and Blackboard, use the search bar feature and the keywords "Investigational New Drug" for the IND course and "Investigational Device Exemption" for the IDE course.

Blackboard-hosted Courses for University of Rochester Students

- Orientation to Requirements for FDA Investigational New Drug (IND) Application
- Orientation to Medical Devices and the Requirements for an FDA Investigational Device Exemption (IDE) Application

MyPath-hosted Courses for University of Rochester Faculty and Staff

- Orientation to Requirements for FDA Investigational New Drug (IND) Application
- Orientation to Medical Devices and the Requirements for an FDA Investigational Device Exemption (IDE) Application

Preparing for an FDA Audit

If you are interested in learning a bit more about what happens during an FDA audit and how you can be prepared for one, watch this short training video.

- Preparing for an FDA Audit