

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.

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Office of Regulatory Support

The Office of Regulatory Support (ORS) offers services to support investigators with the navigation of and compliance with a range of governing requirements. In addition to general assistance with requirements as they arise, expertise is provided to support specific FDA-regulated processes, including research involving experimental drugs and devices, as well as preclinical laboratory studies.

Investigational Drugs Guidance for FDA IND	Investigational Devices Guidance for FDA IDE
Regulatory Science Research and Education	ClinicalTrials.gov Guidance for Required Reporting
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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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Expanded Access

Expanded access, sometimes called compassionate use, is the use of an investigational medical product (that has not been approved by the FDA) outside of a clinical trial. The FDA allows these uses on a case-by-case basis, when submitted by a qualified physician.

In order for the FDA to permit expanded access to an investigational drug, the following criteria (found in 21 CFR 312.305(a)) must be met:

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; and
3. providing the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

This process involves the careful coordination of information with several groups at the University:

- Office of Regulatory Support (ORS)
- Office of Research and Project Administration (ORPA)
- Office of Counsel
- Research Subjects Review Board (IRB)

bit.ly/Expanded-Access

Apply for Expanded Access

To use expanded access, please submit an [Expanded Access Application](#). Someone from the Office of Regulatory Support will be in touch with you soon to provide assistance so that the regulatory process and reporting obligations are understood and fulfilled.



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

The screenshot shows two fields from the FDA Form 1571. Field 7A is titled "7A. (Proposed) Indication for Use" and contains a large text input area. To the right of the input area are two checkboxes: "Is this indication for a rare disease (prevalence <200,000 in U.S.)?" with "Yes" and "No" options, and "Does this product have an FDA Orphan Designation for this indication?" with "Yes" and "No" options. Below these checkboxes is a text input field for "If yes, provide the Orphan Designation number for this indication:". To the right of this field is a yellow button labeled "Continuation Page for #7". Field 7B is titled "7B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)" and is currently empty.

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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](#)