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## Regulatory Support.....

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Make a Gift

Home

Clinical & Translational Science Institute / Clinical Research



# Regulatory Support

Make a Gift

Home

Clinical & Translational

Investigational

Devices

Support

Training

Regulatory

Support

## Expanded Access

Investigational  
Devices

Investigational  
Devices

Preclinical Studies

The Office of Regulatory Support (ORS) provides a variety of services to support development of investigational

New Drug (IND)

Investigational New Drug (IND) applications as the Regulatory Sponsor and to

Support for  
Clinical Trials.gov  
Study Registration

An IND Training course, designed to provide local require

MVP Path. This training will take less than an hour and is required for any investigator who will be submitting for who currently

FIGURE

Process

Investment

Training

Investigational New Drug (IND) applications as the Regulatory Sponsor and to

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## Regulatory Support

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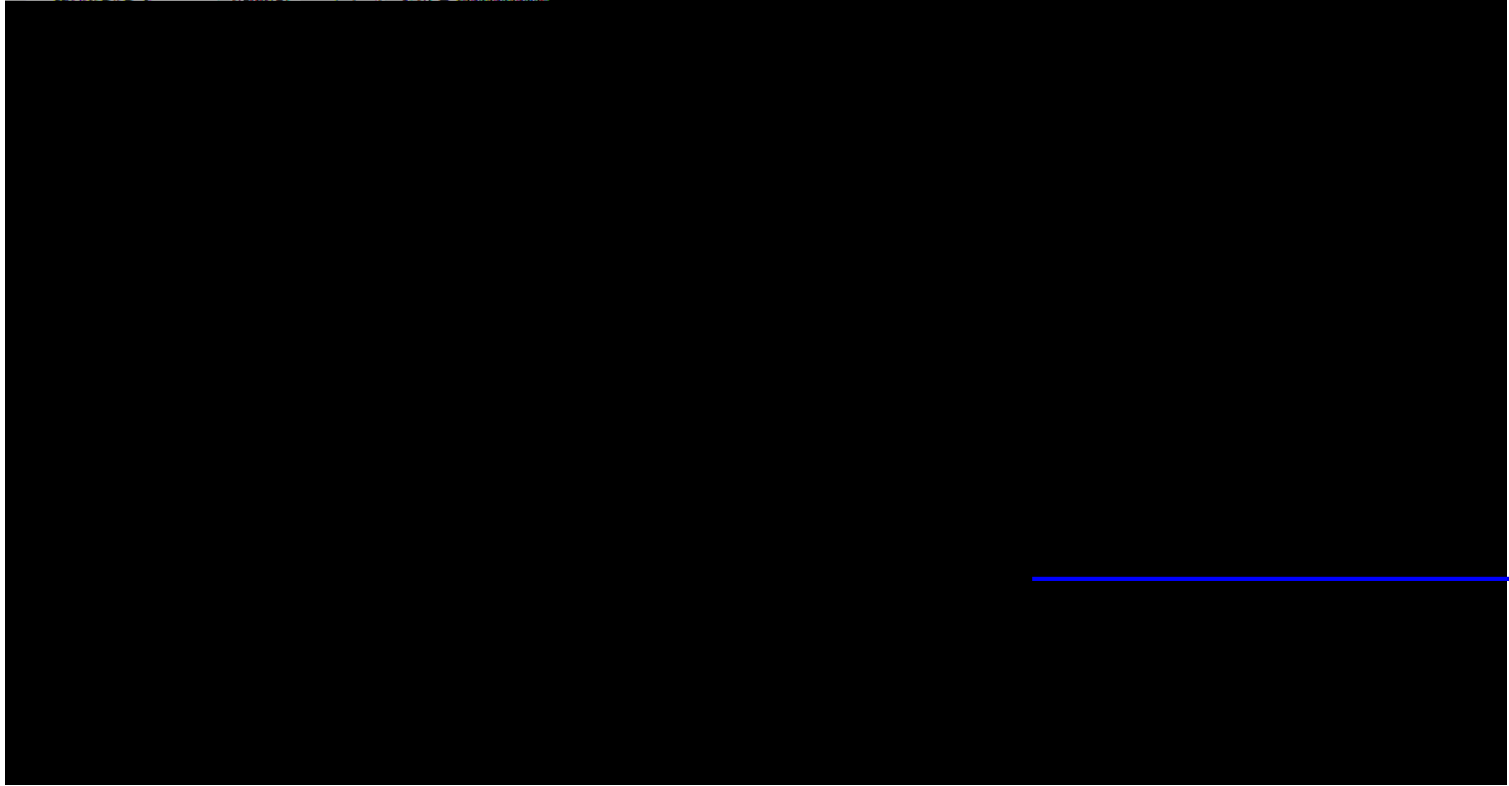
[Home](#)

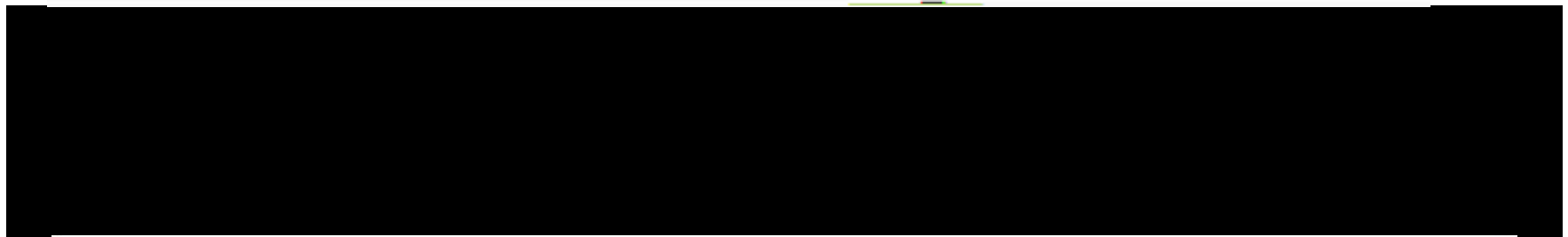
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[Investigational](#)



ed compassionate use is the use of an investigational medical product (that has not been approved by the FDA) for a patient with a life-threatening condition. Expanded access, sometimes call





Stentauzei nomenclaturii (SNOMED CT)

SNOMED CT - the most comprehensive

Orphan Designation for this

Application Disc

# Regulatory Support

The screenshot shows a website with a dark navigation bar at the top containing links for "Home", "Training", "Investigational Drugs", and "Trail". Below the navigation bar, there are several sections. A prominent section titled "Preclinical Studies" is visible. Below this, there are links for "Orientation to Requirements for FDA Investigational New Drug (IND) Application" and "Orientation to Medical Devices and the Requirements for an FDA Investigational Device Exemption (IDE) Application". The text "21 CFR Part 11" is also visible. At the bottom of this section, there is a "Process" button.

This screenshot shows a section of a website with a red circle highlighting the text "and Staff". Below this, there is a heading "MyPath hosted Courses for University of Rochester Faculty" and a list of courses: "Orientation to Requirements for FDA Investigational New Drug (IND) Application" and "Orientation to Medical Devices and the Requirements for an FDA Investigational Device Exemption (IDE) Application". A "Staff Information" button is also visible.

The screenshot shows a text block with the following content: "If you are interested in learning a bit more about what happens during an FDA audit and how you can be prepared, visit our training videos." Below the text, there is a link: "Discover how our FDA Audit...".