

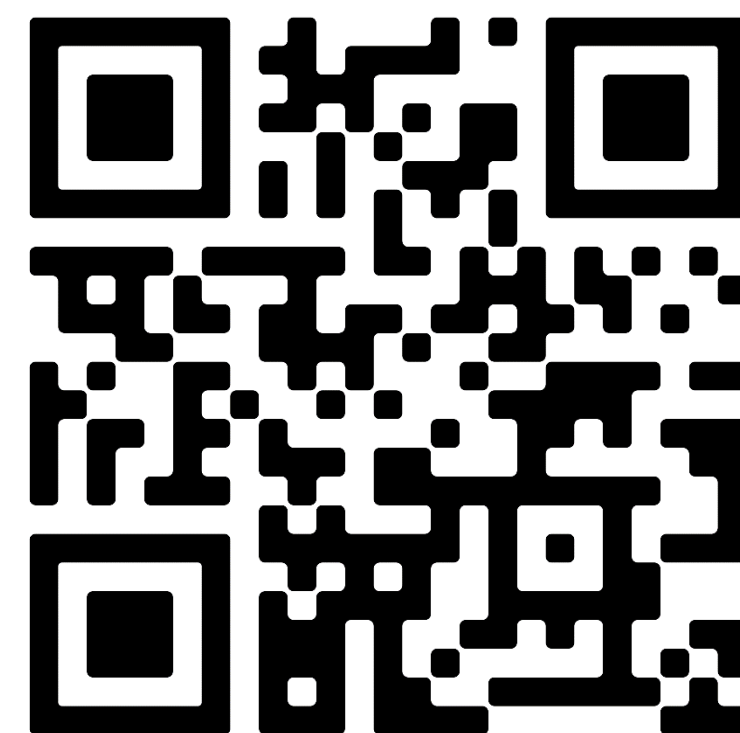
Role of the Office:

The **ICTR Research Ethics Consultation Service (RECS)** provides advice and support for investigators as they **address ethical questions and concerns that arise during study design, execution, analysis, and publication.**

The **ICTR Drug and Device Resource Service (DDRS)** provides JHU investigators and study teams access to resources needed **to help manage the development and use of investigational drugs, biologics, devices and software in clinical research.**

Research Ethics and Regulatory Consultations

Scan to Learn More



Requests for assistance from both the **Research Ethics Consultation Service (RECS)** AND the **ICTR Drug and Device Resource Service (DDRS)** may be submitted by selecting the desired service from the menu in the **Connection Request system.**

DDRS assistance requests can also be Emailed to ICTR_Navigators@jhmi.edu

Services Provided:

The **Research Ethics Consultation Service (RECS)** is currently available for guidance with topics such as:

- Determining appropriate interventions to include in studies;
- Maintaining confidentiality in recruitment;
- Using alternative approaches to informed consent; and
- Responding appropriately when an unforeseen event occurs during data collection.

The **DDRS** provides consultative support for topics including:

- Does my study need an IND/IDE?
- IND Exemption Requests
- Pre-IND/IDE Meetings
- IND /IDE Application Filings
- IND/IDE Submissions (Annual Reports, Information Amendments)
- Compassionate Use INDs/IDEs (including emergency use)
- Drug and Biologic Manufacturing Questions
- Gene Therapy Study Requirements (RAC Applications)