

# IND/IDE Service and Registry

## Translational Research Program

The goal of the TRP IND/IDE Service and Registry is to provide a centralized resource of information, expertise and support related to the complex regulatory requirements, obligations and responsibilities that govern the conduct of clinical research.

### **IND/IDE Registry – What is it and what is in it for me?**

- **The IND/IDE Registry is a web-based listing of open INDs/IDEs at CHB**
- **Registered IND/IDE studies will receive the follow assistance from the Service:**
  - Reminders to you when annual reviews are due to the FDA;
  - Guidance and assistance to you in preparation of required documents.

This also provides the institution with a record of IND/IDE studies in case of audit.

### **IND/IDE Service**

Below details just some of the assistance the IND/IDE Service can provide your research team:

- **Determine whether the product used in your study is FDA regulated, therefore**
  - If an IND/IDE is required in order to conduct your research project
- **Help develop a proper regulatory strategy**
  - Determine whether a Pre-IND/IDE meeting with the FDA would be useful and assists PI's in making these initial arrangements with the FDA
  - Timetable for the submission of required IND/IDE reports to FDA
  - Advice on additional regulatory approvals that may be required and when they should be submitted
- **IND/IDE preparation and submission**
  - General Requirements for the IND/IDE application, such as Content and Format
  - Preparation and Submission of your IND/IDE application
- **Keeping your IND/IDE updated and in compliance**
  - Assist researchers with FDA communications, including: Annual Reviews, Protocol Amendments, IND Safety Reports, and properly closing studies with the FDA

For regulatory assistance with your current or potential research project, please contact the TRP IND/IDE Service, which will be glad to assist you in these matters.

#### **IND/IDE Service – Contact Information**

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