IND/IDE Registration Instructions

Which application types must be registered?

At this time, we are requiring registration of IND and IDE applications connected to a human subjects, clinical trial protocol.

We are not requiring registration for the following types of studies:

- Compassionate Use
- Emergency Use
- Single Patient Expanded Access
  (multiple patient/subject Expanded Access applications must be registered)
- Humanitarian Use Device
- IND Exempt
- Non-Significant Risk Device

How do I register my IND or IDE?

Provide the information below by email (FDA-Regulated-Research-Oversight@lists.wisc.edu) or enter the information in an IND/IDE Registration Survey available at: https://is.gd/indideregistration

For our institutional IND/IDE tracking, we request the following information:

1) * Identify application type: IND or IDE
2) * Name of the individual that holds the IND or IDE
3) * Name of the Principal Investigator
   (This could be the same or different from the IND/IDE holder name)
4) * Protocol Title
5) * Name or description of the investigational drug(s) or device(s):
6) * If IND/IDE Application Has Been Submitted:
   - IND/IDE Submission Date
   - IND/IDE Number(s)
   - IND/IDE Activation Date
7) A Copy of the Protocol
8) A Draft or Completed FDA Form 1571
9) * IRB number: (Enter Pending if IRB number has not yet been assigned)
10) * Anticipated Enrollment Start Date

A member of the FDA Regulated Research Oversight Program team may contact you following completion of the IND/IDE Registration process if clarification or additional information is needed.