IND/IDE Registration Instructions

Which application types must be registered?

At this time, we are requiring registration of IND and IDE applications held by UW-Madison faculty 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 (ind_ide_registration@lists.wisc.edu) or enter the information in an IND/IDE Registration Survey available at: https://is.gd/indideregistration

For our institutional IND tracking, we request the following information:
1) * Select application type: (IND or IDE)
2) * IND or IDE Number(s): (Enter Pending if the IND or IDE number has not yet been assigned)
3) * Name of the individual that holds the IND or IDE:
4) * Name of the Principal Investigator(s):
5) * Clinical Protocol Title(s):
6) * IRB number(s): (Enter Pending if IRB number has not yet been assigned)
7) * Name or description of the investigational drug(s) or device(s):
8) Date of IND or IDE Activation:
*Indicates required data.

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.