

Form of Notice by IND/IDE Holder

Study Title:

IRB Protocol No:

IND/IDE Number:

CU Faculty IND/IDE Holder:

Principal Investigator (if different from IND/IDE Holder):

The undersigned IND/IDE holder will be acting as the Sponsor-Investigator, or the Sponsor with the undersigned Principal Investigator, of the above named study. The undersigned IND/IDE holder acknowledges that as a Sponsor-Investigator or Sponsor of such study, he/she has additional responsibilities under the FDA regulations and confirms that he/she has adequate resources to fulfill such responsibilities in full compliance with such regulations.

IND/IDE Holder:

Name:

Signature:

Date:

Acknowledged (if applicable):

Principal Investigator

Name:

Signature:

Date: