

**Fiscal Year 2019 Investigational New Drug (IND)
or Investigational Device Exemption (IDE)
Documentation Form**

CDMRP Log Number: _____

Principal Investigator's (PI's) Name (please print): _____

Title of Application: _____

I hereby certify that, for the proposed study (select one below):

1. An IND application:

- Has been submitted and has been accepted by the U.S. Food and Drug Administration (FDA).

IND Number: _____

IND Indication(s): _____

- Has been submitted to the FDA prior to the grant application submission.

Date of submission: _____

Current status: _____

2. An IDE application:

- Has been submitted and has been accepted by the FDA.

IDE Number: _____

IDE Indication(s): _____

- Has been submitted to the FDA prior to the grant application submission.

Date of submission: _____

Current status: _____

3. An IND/IDE has not been submitted.

An IND/IDE will be submitted within 60 days of award. *Please attach evidence to support that initial preparations are underway including but not limited to a summary of a pre-IND or pre-IDE meeting with the FDA, a pre-IND/pre-IDE meeting request to the FDA, or other communication with the FDA.*

An IND/IDE is not applicable to the proposed study. *Please attach an explanation and/or documented communication from the FDA or Investigational Review Board of record.*

Signature of PI: _____ Date: _____