

**Fiscal Year 2018 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 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: \_\_\_\_\_