### Medicare Investigational Device Exemption (IDE) Preauthorization Request Cover Letter

**Date:**  **required**

**From: PI name required**, Principal Investigator

 Department of      , Division

 Phone: (650)       Fax: (650)       Email: **required**

 **Study Coordinator Contact Information:**

 **RC name**, Research Coordinator, Department of

 Phone: (650) **required** Fax: (650)       Email: **required**

**To: Director, Coverage Analysis Group**

 **Centers for Medicare and Medicaid Services**

 **ATTN: Clinical Study Certification**

clinicalstudynotification@cms.hhs.gov

 Email **subject line** must state “IDE Preauth Request: IDE #..., SPO#....”

**Cc**: **required** , Clinical Trials Research Process Manager

 Phone:       Fax:       Email: **required**

IDE No.: **required**

Study Title: **required**

Study Nickname:

Study device name: **required**

CMS Category: **required** i.e., A, B, B-1, B-2, B-3 (located on IDE letter from FDA)

Sponsor: **required**

SPO number: **required**

IRB ePro. number: **required**

**Attachments:** You **must include all the attachments** that are specified on the “Medicare IDE Preauthorization Checklist” or your request for preauthorization submission will be returned.

       **I confirm** that I have included the Medicare IDE Preauthorization Checklist and all the documents identified on the checklist.