### Medicare Investigational Device Exemption (IDE) Preauthorization Notification of Study Participation Cover Letter

**FDA IDE Approval Letter dated on or after January 1, 2015**

**(To be completed by the research team)**

NOTE: This letter is to be used when the IDE Acknowledgement letter is dated January 1, 2015, or later, and sponsor has obtained CMS approval.

Date:  required

From: PI name required, Principal Investigator

Department of      , Division

Phone: (650)       Email: required

Study Coordinator Contact Information:

RC name, Research Coordinator, Department of

Phone: (650) required Email: required

To: Marija Cerelli, SHC Stanford Patient Financial Services, at [MCerelli@stanfordhealthcare.org](mailto:MCerelli@stanfordhealthcare.org) Email subject line must state “IDE review request dated 1-1-15 or later: IDE #..., SPO#....”

Cc: required , Clinical Trials Research Process Manager

Phone:       Email: required

Requirements for Noridian to establish records to allow appropriate billing:

1. Stanford hereby notifies Noridian that the PI referenced above plans to enroll subjects in the study entitled (title of protocol):
2. Study IDE designator assigned by the FDA:
3. Study Clinical trial number as listed on [www.clinicaltrials.gov](http://www.clinicaltrials.gov/):
4. PTAN of the facility: (hospital to provide this information)
5. Name of the PI and other participating study MDs and their NPIs:

PI (name//NPI):

Other MDs (names/NPI):

Such notice is necessary to input into the Noridian claims payment systems to assure proper processing of our provider's claims related to such trial. For further information on this process, visit the CMS website: <http://www.cms.gov/Medicare/Coverage/IDE/index.html> his link takes you to an external website..