FDA Approved Investigational Device Exemption (IDE) Pre-Approval Data Submission Request

Please submit the following *required* information to the Contractor for review:

Note: The verification of and validity of all documentation remains the provider's responsibility as is the guarantee that Medicare is billed according to Medicare guidelines.

Device ("G") number_____

☐ **1.** The name of the device (both trade, common or usual and classification name) and a narrative description of the device. Include a statement as to the devices similarities and differences from other products if not explicitly and clearly indicated in submitted documents.

☐ **2.** A copy of FDA approval letters provided to the provider and/or the sponsor or manufacturer of the device.

☐ **3.** A copy of the approval letter from the Provider's Institutional Review Board (IRB). (A copy of the approval letter for any time extension or other update must also be submitted after the initial approval occurs.)

☐ **4.** A description of the action(s) taken to conform to any applicable FDA and/or IRB special controls and/or other requirements.

☐ **5.** A copy of the study protocol, including patient inclusion criteria.

☐ **6.** A sample of the patient consent form**. Form must clearly disclose the receipt of any payment(s) from the sponsor to facility and/or Principle Investigator (PI).**

☐ **7. A** copy or description of the Provider's protocol for obtaining informed patient consent.

Please have the following information available for submission ***on request only*:**

☐ **8.** Copies of *all* agreements between the sponsor and the provider, especially but not limited to, financial agreements, *any and all* payments for *each aspect* of the study.

☐ **9.** The Principle Investigator's (PI's) budget for the study, showing allocation of all funds from all sources**.** The budget should specify both the costs of the services (including evaluations), tests and procedures that will be performed

throughout the course of the study and which will be billed to Medicare. Submit the PI's determination of which tests and procedures are necessary to the "research" and which tests and procedures are "standard of care" for the treatment of the underlying disease in the absence of the study intervention.

[The provider may elect to delineate the Medicare-billed services on the study protocol itself or follow the procedure described in #9 above. On the protocol copy, for *each* service or procedure in the protocol, indicate next to the service or procedure either the word "study" to indicate the service or procedure is a cost and responsibility of the study (and will *not* be billed to Medicare) or the word "Medicare" for a service or procedure which (a) is medically necessary for the patient's care, (b) would have been incurred in the absence of the study and (c) is an Medicare-covered benefit/service.]

☐ **10.** A description of the facility's processes/procedures for ensuring that Medicare is not billed for any non-routine care costs and sponsor or other reimbursed costs.

Consideration for approval of the device will occur *only* after receipt of *each* of the above *completed* items.

PLEASE COMPLETE THE FOLLOWING

Provider (Facility) Name & Oscar Number: _____

Primary Contact Person

Name & Position_____
Address: _____
Telephone Number: _____
E-mail: _____

Secondary Contact Person

Name & Position_____
Address: _____
Telephone Number: _____
E-mail: _____

☐ E-mail Notification of Decision

Or

☐ Mail Notification of Decision

IDE form created by NAS This form is not required, however providers may utilize to assist with providing the required documentation for submission.

Send all requests using the following:

Electronic submission, all states: iderequests@noridian.com

Mail (US, UPS or FedEx)

States: AK & WA

Noridian Administrative Services, LLC
Attn: IDE Part A
PO Box 6720
900 42nd Street South
Fargo, ND 58103-6720

States: ID & OR

Noridian Administrative Services, LLC
Attn: IDE Part A
PO Box 6726
900 42nd Street South
Fargo, ND 58103-6726

State: MN

Noridian Administrative Services, LLC
Attn: IDE Part A
PO Box 6714
900 42nd Street South
Fargo, ND 58103 -6714

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