

# Local Coverage Article: Investigational Device Exemptions (IDE) - IDE Documentation Requirements for Studies with an FDA Approval dated January 01, 2015 or later (A54919)

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## Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01111 - MAC A	J - E	California - Entire State
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01112 - MAC B	J - E	California - Northern
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01182 - MAC B	J - E	California - Southern American Samoa
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01211 - MAC A	J - E	Guam Hawaii Northern Mariana Islands American Samoa
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01212 - MAC B	J - E	Guam Hawaii Northern Mariana Islands
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01311 - MAC A	J - E	Nevada
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01312 - MAC B	J - E	Nevada American Samoa California - Entire State
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01911 - MAC A	J - E	Guam Hawaii Nevada Northern Mariana Islands

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## Article Information

### General Information

<b>Article ID</b> A54919	<b>Original Article Effective Date</b> 10/01/2015
<b>Article Title</b> Investigational Device Exemptions (IDE) - IDE Documentation Requirements for Studies with an FDA Approval dated January 01, 2015 or later	<b>Revision Effective Date</b> 10/01/2015
<b>AMA CPT / ADA CDT / AHA NUBC Copyright Statement</b>	<b>Revision Ending Date</b> N/A
	<b>Retirement Date</b> N/A

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## Article Guidance

### Article Text:

Effective January 01, 2015, CMS Coverage Analysis Group began reviewing all IDE trials for approval. Once CMS approves the trial they list the trial on their web site as approved. This process is streamlining the approval process for all parties involved.

Noridian has reviewed our requirements for such studies. For IDE trials with an FDA approval letter on or after January 01, 2015 that have been approved by CMS Noridian will only require:

1. Notice of participation in the trial,
2. IDE designator assigned by the FDA
3. Clinical trial number as listed on [clinicaltrials.gov](http://clinicaltrials.gov)

A letter including the three above stated requirements along with the PTAN of the facility, the names of the principal investigator, study doctors and their NPIs is to be submitted at time of request to Noridian.

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 please visit the CMS website: [CMS website](http://CMSwebsite)

### **IDE Documentation Requirements for Studies with an FDA Approval dated prior to January 01, 2015**

For any IDE trial with an FDA approval letter date before January 01, 2015, Noridian will continue to require the following documentation:

1. Name of the trial, the assigned FDA IDE number and the Clinical Trial number;
2. The study protocol;
3. The most recent institutional IRB approval letter;
4. The most recent IRB approved informed consent which includes a financial disclosure for the facility and investigators;
5. For the purposes of an IDE approval the following financial disclosures **shall** be included in the informed consent and be clearly marked as such therein:

- Funding source(s) for the project;
- Funding for the facility;
- Funding for the investigators and if that funding is direct to the provider or if the facility is provided funds to offset his/her salary
- Any relationship that the provider has with the sponsor. These include but are not limited to being a speaker for the sponsor, receiving other gratuities from the sponsor and/or being a paid consultant for the sponsor.
- Other financial interests in the sponsor(s) such as stocks or other investments;
- Any other potential conflict of interest as it regards the respective study;
- Any such interest as disclosed to the Institutional Review Board.

The informed consent does not necessarily need to include the extent of such potential conflict (e.g. how many stocks the institution/ primary investigator (PI)/ secondary or other investigators (SI) has from the sponsor or the actual monies paid directly to the institution/PI/SI) only that one exists. Noridian does reserve the right to request a budgetary review of IDE trials/studies but the latter does not need to be submitted with the application.

Failure to provide such information either in the affirmative with a listing of such items or in the negative (no known conflicts) will result in a denial of the request. The provision of fraudulent information will be referred to Medicare enforcement agencies.

#### **Form**

[FDA Approved IDE pre-Approval Data Submission Request](#)

#### **IDE Submissions**

All IDE submissions regardless of FDA letter date should be sent to one of the following:

Email: [iderequests@noridian.com](mailto:iderequests@noridian.com)

Hard Copy:

ATTN: IDE Coordinator

PO Box 6782

900 42nd St. S

Fargo, ND 58103-6722

For those IDE studies with an FDA approval letter dated **before** January 01, 2015, provider notification will be sent out upon approval/disapproval. If an application is approved, the system will be set to accept a provider's claims.

For those studies with an FDA approval letter dated on or after January 01, 2015, a notice of receipt of the information and confirmation that the study has been vetted by CMS will be sent to the provider.

#### **Resources**

Providers should adhere to the CMS billing requirements to ensure the proper processing of IDE claims.

[CMS Internet Only Manual \(IOM\), Publication 100-4, Medicare Claims Processing Manual, Chapter 32, Section 68 IOM, Publication 100-02, Medicare Benefit Policy Manual, Chapter 14, Section 20](#)

[Federal Register Vol. 78, No. 237](#)

[CMS Change REquest \(CR\) 8401](#)

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## **Coding Information**

## Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

## Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

**CPT/HCPCS Codes** N/A

**ICD-10 Codes that are Covered** N/A

**ICD-10 Codes that are Not Covered** N/A

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## Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
10/01/2015	R3	Removed URL Link referring to CMS Chapter 14 Medical Devices as it would not open and was a duplication.
10/01/2015	R2	Typographical Error: HTML format change so link to clinical trials.gov would open; Added PO Box and the word Coordinator.
10/01/2015	R1	R1- Revised to correct link and PO Box number

[Back to Top](#) **Related Local Coverage Document(s)** N/A

**Related National Coverage Document(s)** N/A

**Statutory Requirements URL(s)** N/A

**Rules and Regulations URL(s)** N/A

**CMS Manual Explanations URL(s)** <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf>

**Other URL(s)** [MLN Matters Article](#)

**Public Version(s)** Updated on 03/15/2016 with effective dates 10/01/2015 - N/A [Updated on 03/10/2016 with effective dates 10/01/2015 - N/A](#) [Updated on 03/10/2016 with effective dates 10/01/2015 - N/A](#) [Updated on 02/18/2016 with effective dates 10/01/2015 - N/A](#) [Back to Top](#)

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## Keywords

- Investigational Device Exception
- IDE
- Clinical trial

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