

INVESTIGATIONAL DEVICE EXEMPTION (IDE) REVISED REQUIREMENTS FOR MEDICARE INTERMEDIARY PRE-APPROVAL

Background Information:

Beginning September 1, 2001 the AdminaStar Federal reduced the documentation previously required to approve IDE requests. The original requirements were published in the July and September 1999 issues of the Part A News. Revision articles were previously published in the March 2000 issue of the Part A News and were on the AdminaStar Federal Web site (www.adminastar.com) in June 2001. The IDE Revised Requirements can be found in the Part A News December 2001, Volume 02-Issue 4. Any provider participating in a clinical study involving a FDA IDE who wants to submit claims for these services must send the following documents to the Medicare Part A Fiscal Intermediary (FI) before coverage can be considered. All items specified below must be submitted to the fiscal intermediary in order to obtain Medicare approval for the facility fee portion of the services rendered as part of the study. Approval must be obtained before claims may be submitted.

The required information listed below must be submitted directly to:

Jewish Hospital
Center For Advanced Medicine
Attn.: Nancy Gentry, CPA
200 Abraham Flexner Way, 6th Floor
Louisville, KY. 40202
Ph: (502) 560-8310
Fax: (502) 587-4630
Email: nancy.gentry@jhhs.org

1. Provider name (Jewish Hospital) and Provider number (180040)
2. The name and number of the device (trade name, common or usual name and classification) and a detailed narrative description of the device.
3. A signed copy of the FDA approval letter to the sponsor demonstrating Category B, IDE status and approval from the FDA to the participating company or manufacturer.
4. The FDA approval letter containing the most current approved number of institutions and subjects, and the number of cases the institution is planning to perform.
5. A copy of the protocol for performing the procedure utilizing the Category B, IDE device and a summary of the results of patients who have undergone the procedure(s) described within the protocol.
6. A copy of the contract agreement between the company or manufacturer and the provider, furnishing the details of provider participation in the study.
7. A copy of at least two peer-reviewed publications (abstracts are not acceptable) addressing the topic of the study.
8. A copy of any product literature illustrating the device and/or the procedure.
9. The protocol used for obtaining informed consent from beneficiaries for their participation in the study. (This is your standard operating procedure for obtaining informed consent)
10. An Institutional Review Board approval letter or a statement from the provider (Jewish Hospital) assuring that approval has been obtained from the study institution.

On a separate page please reference the complete title of the study, study number, if available, the Principal Investigator and the name and contact number of the person submitting this information.

For additional information please contact the Jewish Hospital, Center for Advanced Medicine at 502-560-8310.