

Investigational Device Exemption Studies Now Reviewed, Approved Centrally by CMS

New process affects all new studies submitted after January 1, 2015

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 allowed Medicare payment of the routine costs of care furnished to Medicare beneficiaries in certain categories of [Investigational Device Exemption \(IDE\) studies](#).

As of January 1, 2015, the Center for Medicare & Medicaid Services (CMS) made changes to the process of obtaining coverage approval for standard of care items and services in a device trial. Previously handled by local Medicare Administrative Contractors (MACs), this process is now managed centrally by CMS.

Investigators should note the following changes as a result of this new process:

- Study teams submitting IDE studies for approval AFTER January 1, 2015 must now go through the central CMS office to obtain CMS Approval Letters. Detailed submission requirements are available [here](#).
- IDE studies approved by MACs PRIOR to January 1, 2015 will continue to be administered by the MAC. Study sponsors should continue to follow the process established by the MAC for any site additions or protocol changes.
- Study sponsors do NOT have to submit their protocol to CMS if the participating study investigator sites have already received approval from their MAC.
- CMS will post information on their website each week for IDE studies approved after January 1, 2015. Study teams are encouraged to [check the CMS website](#) to see if their site has already been approved prior to submitting a new application.

To speed up the submission process, CMS has released a [Checklist and Sample Crosswalk](#). Submitters are encouraged to submit the crosswalk along with the request packet to facilitate CMS' review. CMS will review each complete submission within approximately 30 days, and e-submissions (emails and/or electronic documents) are preferred over hardcopies.

Questions?

Please contact the Clinical Research Calendar Review & Analysis Office via [email](#) or phone at (734) 998-6880, or visit the [CMS website](#) for more information.