# Local Application Process For Medicare Coverage Of IDE

## Applies to IDE studies with FDA approval letters dated prior to 1/1/2015

Applications are submitted to Noridian Healthcare Solutions.

## What the UW Medicine study team *must* do

After all of the budget and billing grid/coverage analysis documents are completed and CTA are completed and the IRB approves the ICF, complete the Noridian application form as instructed below:

Form Instructions: The Noridian IDE pre-approval application form now covers both Part A (hospital) and Part B (professional) services. The hospital Provider (Oscar) Numbers are: HMC: 500064; and UWMC: 500008.

Email the completed Noridian pre-approval application form and the Investigator-signed form(s), along with the following documents (in separate files) to the Clinical Research Budget and Billing Office (CRBB) – Clinical Trials Office (CTO):

- Name of Device
- FDA approval letters (no redactions)
- IRB approval
- Actions taken to conform to FDA or IRB special controls or requirements
- Study Protocol
- ICF—this must address any payments (or lack of payments) from sponsor to facility/PI
- SOP for obtaining Informed Consent
- Coding used to describe the service (facility and professional)
- CTA and all contract-related documents between Sponsor and UW.
- Budget and billing grid/coverage analysis documents
- CRBB-CTO will provide: description of how UW Medicine ensures accurate billing in studies.

Once all required documents and completed/signed application forms are received, CRBB-CTO submits the packet to Noridian for review.

- The study may not begin subject enrollment until Noridian approval is obtained, keeping in mind that it must also complete all of its IRB, CRBB-CTO, and CTA/Contract review processes before it will be cleared by the CRBB-CTO to do so.