

COLUMBIA UNIVERSITY MEDICAL CENTER
Instructions for NGS Submission
To Request Coverage Decision

Investigational device studies under an FDA-issued IDE that begin with the letter “G”, and post-market approval studies or registries of carotid stents, must be submitted to the Medicare contractor, National Government Services (NGS), for a coverage decision prior to enrollment of subjects into the study.

Submission to NGS cannot occur until the protocol has received IRB approval and the contract for the study has been signed by all parties.

Prior to having the IRB approval documents and executed contract available, you can determine whether you need to submit a full application, or if you can use a short application. A full application includes documents that you can collect prior to having IRB approval – minimizing the time it will take for submission to NGS.

To determine which submission is required, send an email to:

NGS-IDE-Request@wellpoint.com

In the subject line, put: Short or Full Application for GXXXXXX/SXX- Columbia University (where GXXXXXX is the IDE number and /SXX is the amendment number, if any).

In the body of the email, enter:

For the study entitled: “*the official study title*” sponsored by “*name of the Sponsor*” is a short or full application needed for NGS determination?

You will receive a reply within a day or two telling you whether a Short or Full Application is required.

The documents (all in electronic form) required for a full application (but not for a short application) include the following:

1. A non-redacted copy of the FDA-approval letter provided to the sponsor or manufacturer of the device. The approved IDE code number and category designation must be on the letter.
2. A description of any action(s) taken to conform to any applicable IDE special controls.
3. A full copy of the applicable protocol (the sponsor’s protocol, not the Rascal study description).

4. A narrative description of the device sufficient to make a payment determination. (If this is part of the protocol, identify the page number(s).)
5. A statement indicating how the device is similar to and/or different from other comparable products. (If this is part of the protocol, identify the page number(s).)
6. At least two (2) supporting scientific articles (full texts) for the investigational device and its intended indication published in peer reviewed literature.

Your responses to items 2, 4 and 5 can be in a single MS Word document.

A short application can be used if NGS has already received an application from another site for the same study. The abbreviated application does not require the documents listed above, only the following items:

The following documents (in electronic form) are required of all applications (both short and long):

1. The Rascal-generated approval certificate.
2. A copy of the approved consent form (this can have the watermark indicating that it is inactive)
3. A copy of the fully executed (i.e., signed) clinical trial agreement – available from the CTO
4. A list of any devices, supplies, drugs or services for which NYP or the study physician will be reimbursed by the manufacturer. (This can be in the form of a MS Word document and may simply reference the specific page in the trial agreement).
5. A Columbia NGS Application form*.

* This is generated within Rascal and can be viewed within your protocol, by clicking the “Print Menu” selection on the left hand rascal menu. The form automatically fills in the following items using data within Rascal:

IDE number (with /SXX)
Protocol Title
Rascal Protocol Number
Device Trade Name
The name of the PI

(N.B. If any of these data are incorrect, please correct it within the Rascal application and regenerate the form.)

To complete this form, you must fill in the following items:

1. Check:
Medicare A – if you plan or may be billing for professional (MD) services

Medicare B – if you plan or may be billing for hospital services

2. The Common name of the device (i.e., carotid stent, implantable defibrillator)
3. The Degree and NPI (National Provider Identifier) number (a 10 digit number) for the PI and for all Co-investigators who may be billing Medicare (you must type in the names of these co-investigators).

If you don't know the NPI number you can look it up at:

<http://www.npnumberlookup.org/>

3. The target accrual at the Columbia site
4. Billing type – select inpatient, outpatient or both from the drop-down menu.

Click the “Generate Filled PDF” at the bottom of this form. You need to save this pdf file to your desktop and give it the name:

“GXXXXXX_DXXXX PI's Name.pdf” ([Where GXXXXXX is the IDE number, DXXXX is the Rascal Protocol number (ignoring the leading AAA) and PI's name]).

When you have this form with all of the required documents, email this to:

devices@columbiaclinicaltrials.org

The CTO will check the application for completion, and submit the completed application to NGS.

Approvals of short applications are typically obtained within 2 to 3 days. A long application may take up to two weeks to receive a determination.

The NGS determination will be forwarded by the CTO to the IRB, the OFBC, and to the PI.