

October 21, 2010

Columbia University Medical Center

Standard Operating Procedure for Medicare Approval of Device Trials

1. When a protocol for a device trial is submitted to RASCAL, the PI must check the “device study” box in the RASCAL IRB module and complete the Investigational Products section. Within the Investigational Products section, the following questions must be answered either “yes” or “no”:

- a. The study has been assigned an FDA IDE number beginning with a “G”.
- b. The study involves a carotid stent.

For purposes of this SOP, the term “Device Trial” is a trial for which the device study box and one of the foregoing (a) and (b) options apply.

2. During the IRB pre-review of a new protocol:

a. If the IRB staff member believes that the trial would qualify as a Device Trial and appropriate RASCAL boxes have not been checked at submission of the protocol, the IRB will return the protocol to the PI with instructions to check the appropriate boxes and resubmit the protocol to RASCAL.

b. If the trial is determined to be a Device Trial, the IRB staff will notify the CTO (using the email address: ngsapproval@columbia.edu), the Office of Billing Compliance (OBC) and the PI that submission to the National Government Services (NGS) is required. The IRB will attach detailed NGS submission instructions (see attached document) to the email notice.

3. At the time of IRB approval of a Device Trial protocol:

a. The consent form for such trial will be automatically de-activated by RASCAL.

b. The IRB approval correspondence will include a statement that the consent form cannot be activated until NGS approval (or other relevant NGS determination) has been received.

4. The PI or the trial coordinator will collect the necessary documentation (as described in the attached document) and submit it to the Administrator of the CTO (using the email address: ngsapproval@columbia.edu) for review and submission to NGS.

5. When the NGS approval (or other relevant determination) letter is received by the CTO:

a. Copies of the letter and the NGS documentation will be attached in RASCAL by the CTO, and the CTO will provide email notification to the PI, the IRB and the OBC that the letter has been received and attached in RASCAL. The CTO will provide similar email notification to the Director of Patient Financial Services at NYP, with a copy of the NGS letter attached.

b. The IRB staff will activate the relevant consent form(s) for the trial.

6. If any of the following events occurs with respect to a Device Trial:

- A voluntary or involuntary decision to terminate participation in the trial;
- IRB re-approval or withdrawal of IRB approval;
- A change in the protocol, informed consent or investigative contract;
- An expansion of the number of anticipated enrollees;
- An extension of the time of the study; or
- An addition to or deletion from the roster of the investigating physicians (including sub investigators)

a. The IRB staff, upon reviewing the modification or renewal which describes the event, will notify the PI, the CTO and the OBC that notice of such event should be sent to NGS.

b. RASCAL will automatically de-activate a consent form when any modification or renewal of a Device Trial is approved. If the submission does not involve a new procedure or an increase in the number of subjects, the IRB staff will re-activate the consent form at the earliest possible opportunity.

c. The PI or trial coordinator will prepare the notice and submit it to the Administrator of the CTO for review and submission to NGS.

d. Copies of the notice will be attached in RASCAL by the CTO and the CTO will provide email notification to the PI, the IRB and the OBC.

e. If a new procedure or an increase in the number of subjects has been approved by the IRB, approval from NGS is required before the consent form(s) may be activated.

7. A monthly report of Device Trials will be generated by the RASCAL help team and made available to the IRB, the CTO, the OBC and NYP.

8. The CTO will maintain a central file of all submission documentation and correspondence with NGS.

9. The IRB Executive Director or Associate Director and the Executive Director of the CTO may exempt any Device Trial from one or more of the foregoing requirements for good cause.