DEFINITION OF MODIFIED PARTICIPATION

Form # 96A

All randomized participants are to be followed until death or the end of study. For each participant, the "end of the study" is defined as the F48 visit, or its "target visit date" if that visit is not completed. Modified participation occurs when a randomized participant a) refuses or is unable to do *all* of what is required for the study but is willing to do *some* of what is required, or b) refuses or is unable to participate in the study at all. Under the intent-to-treat policy, all such participants must continue to be followed, as much as possible, until death or the end of the study. The participant's chart must contain source documentation of the decision to modify participation, including the level of continued participation agreed to (selected from the options available). Modified Participation Form 28 must be entered within two weeks of the event. Form 28 need not be entered when a study endpoint is met.

It is desirable that modified participation be streamlined in such a way as to meet the study's endpoints while sufficiently reducing participant burden. To this end, Section 12.6 of the protocol outlines the plan for modified participation. In addition, the Modified-Participation Checklist has been created for the clear and consistent interpretation of these guidelines across sites, and to serve as source documentation if permitted by the institution.

When participation is modified, it is recommended that the participant be re-consented in some fashion, although some sites may require nothing more than documentation of the changes in a progress note. The re-consenting process may vary across institutions according to local requirements. Some sites may allow investigators to modify the original consent form, while others may require a new consent form listing which activities the participant does and does not agree to complete.

The Modified-Participation Checklist has been designed as an optional tool for participants, coordinators and local IRBs. Its function is to help all parties consistently interpret the options/requirements of modified participation in the study. Depending on institutional guidelines, sites may need IRB approval of the checklist. It is recommended that coordinators administer the checklist to ensure participants' understanding of the requirements for continued participation in the study. If approved by the local IRB, participants may be asked to sign the form instead of, or in addition to, a signed consent.

A summary of reporting requirements for participants who have modified participation has also been created to assist coordinators and investigators. Refer to the cheat sheet titled "Modified Participation Follow up Due."