

Closure to Enrollment - Frequently Asked Questions

- 1. When is the study closing to patient enrollment?** *Based on the statistical center's calculations, the project team has set December 7 as the date for closure to enrollment.*
- 2. When is the last date that a participant can be scanned?** *30 days after the pre-PET submission date. If registration closes December 7, then the pre-PET may be submitted until Dec 14 and the PET scan would need to be completed by January 13.*
- 3. How do I avoid having the case cancelled after I register a participant?** *The protocol is very clear about the deadlines and they are included below, for your reference:*
 - **The Pre-PET Form** must be received within 7 days of the case registration or **the case will cancel.**
 - **The Amyloid PET scan** must be completed within 30 days of the Pre-PET submission date or **the case will cancel.** Scans conducted prior to submission of the Pre-PET case report form are **INVALID.** The PET Completion Form must be submitted by midnight of the scan date and the PET Report Form and PET Assessment Forms must be received within 7 days of the scan date.

Since all PET scans will have been completed within 30 days of enrollment closure, we anticipate closing the database to new data submission approximately 40 days after the enrollment closure date.

- 4. Will re-registration of a case be available to referring physician practices if the PET scan is not completed within 30 days of the pre-PET form submission?** *Unfortunately, that process will no longer be available once enrollment has closed. Please be sure that participants, staff, PET imaging facilities and referring physician practices are aware.*
- 5. What happens if a participant misses his/her scheduled PET scan? What if we can't get a participant scheduled for their PET scan before the deadline? What happens if the dose gets cancelled for a participant who is scheduled close to the deadline?**

As long as the 30 days has not elapsed, the patient may be re-scheduled. However, if the next available scheduling slot is AFTER 30 days, the participant will not be allowed to be re-registered by the dementia specialist. We encourage dementia specialists to check on any scheduling limitations or special considerations prior to scheduling participants in November and December.
- 6. I am at a PET Facility; anything particular I need to do?** *Yes, please be sure that all data required from your PET facility have been submitted within the timelines required by the protocol (PET Completion Form by midnight on the day of the scan and the PET Report Form and PET Assessment Forms within 7 days after the PET scan) so that you can submit a valid claim to Medicare for reimbursement.*

7. When do I submit a STUDY CLOSE OUT to the Institutional Review Board? *The IDEAS Study Operations Center will advise you of this date once the study has actually closed to enrollment, all PET scans have been completed, and the database is closed for data submission. We anticipate first quarter 2018.*

8. Should I expect a termination letter from ACR as regards the contract now that the study is ending? *At this point, only study enrollment is closing. You will be advised about study closure in the future.*

9. Will my PET facility have our escrow account reimbursed? *Yes, any remaining balance in the escrow account will be reimbursed when the overall study has closed. Details are presently being worked out.*

10. When will the last payment be made to referring physician practices? *The last payment is anticipated on January 31, 2018 based on data collection as of December 31, 2017.*

11. I'm interested in publishing a paper using the data we collected at our site for the IDEAS Study. Are there any approvals that I need to obtain? *Yes. All publications shall be submitted for review and comment by the IDEAS Research and Publications Subcommittee (IDEAS-ResearchPub@acr.org). Per contract, results based on individual site data collected as part of the IDEAS Study may be published provided that: (1) the primary aim manuscript for the IDEAS Study has been accepted for publication; and (2) the publication aims of the institution do not overlap with the Study's primary and secondary objectives as outlined in the Protocol. However, note that these restrictions do not apply to the amyloid PET scans or their clinical interpretations, which are considered clinical data and may be used for research purposes by sites with appropriate institutional IRB approval.*

12. Will there be another study? *The IDEAS Study investigators are exploring other options regarding the clinical utility of amyloid PET, and we will provide updates as information becomes available.*

13. How long do I need to save documents related to the study (signed informed consent documents, etc). *Guidance from the National Institutes of Health recommends that records be retained for three (3) years after the completion of a study. The IDEAS Study is closing to new participant enrollment, but it is not anticipated that the study will be complete for several years yet.*