

ACRIN – 4003 FORM COMPLETION INSTRUCTIONS

Protocol Deviation Form

PR Completion Instructions

The PR form is to be completed when a protocol requirement is not met. Complete a separate form for each case and for deviation. Please refer to the Protocol for further details.

1. Study Time Point *Please verify the correct time point is selected since subsequent web entry may be affected.*

- (1) Visit 1: Clinical Evaluation
- (2) Visit 2: Imaging Visit
- (3) Visit 3: Imaging Visit (if applicable)
- (4) Follow-Up: Day 1 Post Imaging

PR Form: in the instance a protocol requirement is not met, PR form must be completed.

Question 1: Must only select one reason for Protocol Event being reported.
If “88 Other” is selected, please specify reason.

Question 1a: You could only select one Imaging Deviations [¹¹ C]-PIB or [¹⁸F]-AV-45.
If “88 Other” is selected, please specify reason.

Question 2: Please provide date the protocol deviation occurred: **MM/DD/YYYY**

Question 3: Please provide date of protocol deviation was discovered: **MM/DD/YYYY**

Question 4: Please describe the protocol deviation.

Question 5: Please provide information on what was done to rectify the situation and or prevent future occurrence.

Question 6: Provide information on time point this deviation applies (select only one).
If “88, Other”, is selected, please specify reason.

Please Initial and Date form

Make sure data was assessed, reviewed and approved by PI