

S54r0 Withdrawal Form Completed after Randomization

Ad Hoc Event ID _____

Visit Date (yyyy/mm/dd): _____

Correction:

- Yes
 No

1. Is patient a crossover or a withdrawal?

- Crossover
 Withdrawal

1A. If crossover, choose type:

- Transfusion --> observation
 Observation --> transfusion

1B. Reason for crossover from transfusion to observation (choose one):

- Non-compliance
 Declined assigned arm
 Progression of lesion
 Time commitment
 Relocation
 Financial constraint
 Other

1B-1. If Other, specify reason: _____

1B. Reason for crossover from observation to transfusion (choose one):

- Non-compliance
 Declined assigned arm
 Progression of lesion
 Time commitment
 Relocation
 Financial constraint
 Other

1B-1. If Other, specify reason: _____

2. Reason for cessation / withdrawal (choose one):

- Non-compliance
 Declined assigned arm
 Progression of lesion
 Time commitment
 Relocation
 Financial constraint
 Other

2A. If Other, specify reason: _____

You must submit a withdrawal letter to your local IRB for all patients who withdraw after randomization.

Staff I.D. #: _____