STUDY TREATMENT DOSING IRREGULARITY

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: [ID] 2. Current Clinic: [SITE]
3. Patient's Letter Code: [INITS] 4. Visit: [VISIT] - sequence # [SEQNO]
5. Date: [VIS_DT] ___ Month - ___ Day - ___ Year

PART II: DOSING IRREGULARITY OCCURRENCE

1. Person initiating request: [PERINREG]
2. Contact Number: ___ - ___ - ___ [CONT_NO]

		YES	NO	
3.	Circumstances of dosing irregularity (Answer each item):			
A.	Medical emergency	(1)	(2)	MEDEMERG
B.	Non-medical emergency	(1)	(2)	NONMEDEM
C.	Possible or real study treatment overdose	(1)	(2)	OVERDOSE
D.	Other	(1)	(2)	DOSOTHER
1.	If other, specify: _____			DOS_SP

PART III: UNBLINDING OF STUDY TREATMENT

		YES	NO	
1.	Was the patient unblinded?	(1)	(2)	UNBLIND

If NO, skip to Part IV.

		YES	NO	
2.	Unblinding would change the clinical treatment of the patient	(1)*	(2)	UNBLCHNG
3.	Unblinding was done by (Answer each item):	YES	NO	
A.	MCC Medical Consultant	(1)	(2)	UNBLMC
B.	Medical Coordinating Center	(1)	(2)	UNBLCC
4.	Individuals informed of the assigned study treatment (Answer each item):	YES	NO	
A.	Principal Investigator	(1)*	(2)	INDPRINV
B.	Clinic Coordinator	(1)*	(2)	INDCOORD
C.	Patient/Family	(1)*	(2)	INDPTNT
D.	Other	(1)*	(2)	INDOTHER
1.	If other, specify: _____			IND_SP
5.	If any*, submit Form 80	(1)	(2)	F80III5

PART IV. COORDINATION

1. Checked for completeness and accuracy:

   A. Certification number: ☐☐ - ☐☐ CERT_NO

   B. Signature: _____ CERT_SIG

   C. General Comments: GEN_CMNT