WORLD HEALTH ORGANIZATION

ADVERSE EVENT REPORT

AER

IDENTIFICATION

a) Form Code [A][E][R]

b) Study Number [| | | |]

c) Centre Number [| | |]

d) Subject Identification Code [| | | |] [ ]

e) AER Report Number [|]

1. Date event first notified to Investigator ___/___/___ Day Month Year

2. Date of report ___/___/___ Day Month Year

3. Description of event

_____

_____

_____ [| | |] [ ]

_____ [| | |] [ ]

4. Date of onset ___/___/___ Day Month Year

5. Date ended ___/___/___ Day Month Year
(888888 if not ended)

6. Duration ***(if less than 24 hours)*** ___:___ hours min

.7. Frequency
1=Intermittent 2= Continuous

8. Severity [ ]
1=Mild 2= Moderate
3=Severe

9. Measures taken
a) Drug or intervention
1=no change-drug or device continued
2=dose reduced (if relevant)
3=drug or device stopped
9=not applicable [ ]

b) Participation in study
1=continuing 2=discontinued or
3=other released from study [ ]

10. a) Other actions [ ]
1=none 2=medication
3=hospitalisation 4=other

b) If "2 or 4", give details

_____

11. Current status or outcome
1= complete recovery
2=partial recovery
3=not yet resolved
4=chronic condition or sequelae
5=death
9=unknown [ ]

12. a) Relation of adverse event to study drug or device (Principal Investigator's assessment) [ ]
1= not related 2= unlikely
3= possibly 4= probably
5= highly probably 9= not assessable, explain

_____

b) If "3, 4 or 5", is the adverse event unexpected (i.e. not described in the Study Protocol, Investigator's Brochure or Guidelines for Investigators as a known side-effect or reaction to the study drug or device)? [ ]

1=no 2=yes

All Unexpected Drug or device Related Adverse Events must be notified to the Study Coordinator within 48 hours. (Fax: +41 22 7914171)

13. Is the adverse event a Serious Adverse Event (i.e. associated with death, admission to hospital, prolongation of hospital stay, persistent or significant disability or incapacity, or otherwise life-threatening)? [ ]

1=no 2=yes

If "yes" complete Serious Adverse Event Report (SAE)

REMARKS

Name of Investigator (capital letters) _____ Signature:_____ Date form completed (dd/mm/yy) __/__/__