{Module Name} Module

Adverse Events

1. Did the participant have any new adverse events since the last visit? Yes □ 1 No □ 0
   If YES, continue.
   If NO, skip to question 16 and sign and date.

2a. Adverse Event Number: ___ ___ ___

2b. Adverse Event Description:
   Max. 200 characters. One adverse event per form. List syndrome components on separate forms.
   ___________________________________________________________________________________
   ___________________________________________________________________________________

3. Type of report: New Adverse Event □ 1 Change in severity of an existing Adverse Event □ 2

4a. Date of onset (or change) of event: (mm/dd/yyyy) ___ ___ / ___ ___ / ___ ___ ___ ___

4b. Time of onset of event: (hh:mm)
   Use 24 hour clock. ___ ___ : ___ ___

5. Study Drug Related:
   Definitely □ 1 Possibly □ 2 Definitely Not □ 3 Unknown □ 9

6. Severity:
   *Lethal □ 1 Life Threatening □ 2 Severe □ 3 Moderate □ 4 Mild □ 5
   None □ 1 Discontinued Permanently □ 2 Discontinued Temporarily □ 3
   Reduced Dose □ 4 Increased Dose □ 5 Delayed Dose □ 6
   Not Applicable □ 8 Unknown □ 9
   If Lethal, a Serious Adverse Event form must be completed.

7. Action Taken Regarding Study Drug:
   *A Serious Adverse Event form must be completed.
OTHER ACTION TAKEN
Questions 8a-8d must be answered.

8a. NONE
   If YES, then 8b-8d must be answered NO, and 8e must be blank.
   Yes ü1
   No ü0

8b. Remedial Therapy — Pharmacologic (OTC or Rx)
   **Yes ü1
   No ü0
   If YES, medications must be listed in 8e.
   If YES, complete a Concomitant Medication Form and enter the Medication Number below.

8c. Remedial Therapy — Non-Pharmacologic
   Yes ü1
   No ü0

8d. Hospitalization
   *Yes ü1
   No ü0
   If YES, a Serious Adverse Event form must be completed.

8e1. Medication Number 1:

8e2. Medication Number 2:

8e3. Medication Number 3:

9. Description of actions or comments:
   Max. 200 characters.
   __________________________________________________________
   __________________________________________________________

10. Outcome:
   Recovered or resolved ü1
   Recovering or resolving ü2
   Not recovered or not resolved ü3
   Recovered or resolved with sequelae ü4
   *Fatal ü5
   Unknown ü9

11. Was Adverse Event Serious?
   *Yes ü1
   No ü0
   If YES, a Serious Adverse Event form must be completed.

12. Is the Adverse Event continuing? (Same event, same severity)
   Yes ü1
   No ü0
   If YES, skip to question 16 and sign and date.
   If NO, continue to question 13.

13. Did the Adverse Event resolve or change in severity?
   Yes ü1
   No ü0
   If YES, continue to question 14.
   If NO, skip to question 16 and sign and date.

* A Serious Adverse Event form must be completed.
** Complete a Concomitant Medication Form and enter the Medication Number.
If an Adverse Event has resolved or changed in severity then either question 14 (duration) OR questions 15a and 15b (date & time of change) must be answered.

If the Adverse Event was less than 24 hours in length, then it MUST be answered in terms of duration of the event (i.e., 000 days, 02 hours, 45 minutes).

14. If the Adverse Event has resolved or the severity has changed, then estimate the duration to the best of your ability.

   Days: __ __ __
   Hours: __ __
   Minutes: __ __

15a. Date of resolution or change in severity: (mm/dd/yyyy)

   __ __ / __ __ / __ __ __ __

15b. Time of resolution or change in severity: (hh:mm)

   Use 24 hour clock.
   __ __ : __ __

16. STUDY CLINICIAN’S SIGNATURE: _______________________________________

   DATE SIGNED: (mm/dd/yyyy)
   __ __ / __ __ / __ __ __ __

Reference: Developed for use in the NIDA Clinical Trials Network.