SAFETY MONITORING UNIFORM RESEARCH FORM

This form has eight parts.

In Part 1, on pages 3 and 4, “Identification, Demographic and Background Information,” patient identification and basic demographic information is obtained along with information about current medications, both psychotropic and other medications, height, weight, rough indices of functioning, etc. This section also contains information about who is making the ratings.

Part 2, on pages 5 and 6, contains a “General Inquiry” to obtain information about possible adverse events, asked using general probes.

Essential Information On Current Medications, page 7, provides a form to indicate each of the child’s current medications. This list is then used to determine which “medication-specific” inquiries are to be done.

Part 3, on pages 7 through 14, contains a series of “medication-specific” inquiries – asking these inquiries depends upon what psychotropic medications that child has taken during the period of assessment (as reported in Essential Information On Current Medications, page 6).

Part 4, on page 15, Part 6, on page 27, comprise a series of clinician “satisfaction” ratings, i.e., their opinions about using the form, Part 5, on pages 16 through 26, comprises Specific Inquiries about adverse events, organized roughly around different body systems. This part concludes with a “Closing inquiry” in which the clinician can ask about any “adverse” events he/she has pre-existing knowledge about or which he/she noticed during the rest of the inquiry.

For each of Parts 2, 3, and 5 informant responses should entered on the SMURF AE Report (CRF) answer sheet which comprises Part 8, which is supplied as a separate booklet.

Part 7, on page 28, comprises the “List of Preferred Terms” which should be used, where possible, when completing the CRF.

A page for entering comments is available as the last page of this booklet.

INSTRUCTIONS

Read project AIMS, Inclusion/Exclusion criteria and Approach on pages 2 and 3.

Complete Part-1, DEMOGRAPHICs, beginning on page-3.

Complete Part-2, GENERAL INQUIRY, beginning on page-5. Note the time that you start this section and the time that you end. Read the prompt questions as written. When a positive symptom is encountered, complete a SMURF AE Report form entering the question number and the name of the AE as the first two data fields on the form. Complete all fields on the SMURF AE Report. Use your own probes to obtain the appropriate information.

After the GENERAL INQUIRY, complete the ESSENTIAL INFORMATION ON CURRENT MEDICATIONS on page 6, indicating each of the medications that the child has taken since the last visit. You will use this checklist to guide you through Part 3, the MEDICATION SPECIFIC INQUIRY, also beginning on page 6.

Complete Part-3, pages 7 to 14, MEDICATION SPECIFIC INQUIRY, by reading the questions for each medication noted in the ESSENTIAL INFORMATION ON CURRENT MEDICATIONS. Record start time. Read initial inquiry questions as written. When a positive symptom is noted, use your own probes to complete a SMURF AE Report entering the question number and the name of the AE as the first two data fields on the SMURF AE Report. Complete all fields on the SMURF AE Report form.

Complete Part-4, Clinician Satisfaction Rating Scale. Record start time.

Complete Part-5, BODY SYSTEM INQUIRY, by reading the questions for each body system, as written. Record start time. When a positive symptom is noted, use your own probes to complete a SMURF AE Report entering the question number and the name of the AE as the first two data fields on the SMURF AE Report. Complete all fields on the SMURF AE Report.

Complete Part-6, Clinician Satisfaction Rating Scale. Record start time.

Use the LIST OF PREFERRED TERMS when enter AE descriptions.

Part 1 – Demographic Information --- page 3
Part 2 – General Inquiry --- page 5
Part 3 – Medication Specific Inquiry --- page 7
Part 4 – Clinician Satisfaction Ratings --- page 15
Part 5 – Specific Inquiry by Different “Body Systems” --- page 16
Part 6 – Clinician Satisfaction Ratings --- page 27
Part 7 – List of Preferred Terms --- page 28
Part 8 – SMURF AE Report forms --- separate booklet
Evaluation of Adverse Events Associated with the Administration of Psychotropic Medications in Children and Adolescents: Testing of the Feasibility and Incremental Value of Different Elicitation Methods

Aims:

1. To compare the feasibility of 2 different methods of assessing adverse events during treatment with psychotropic medications in children and adolescents.

2. To collect descriptive data on the possible incremental clinical value of adding a systematic inquiry of possible adverse events to an initial general inquiry approach.

Inclusion Criteria:

1. Age between 6.0 and 12.9 years
2. Either sex
3. Current treatment (i.e., child has received at least one dose of medication prescribed) with one or more psychotropic medications (i.e., stimulant, antidepressant, antipsychotic, mood stabilizer, anxiolytic, or adrenergic agent) used for the treatment of a behavioral or emotional disorder.
4. Recent initiation (within 60 days) of the treatment with psychotropic medications, recent addition (within 60 days) of a psychotropic medication to an existing one, or recent increase (within 60 days) in the dosage of a psychotropic medication previously prescribed.
5. Outpatient status

Exclusion Criteria:

1. Child has been on the same medications and same doses for longer than 60 days

Concurrent use of non-psychotropic medications (e.g., antibiotics, anti-asthma) is NOT an exclusion criterion. The name and doses of these concurrent medications will be recorded as part of the interview conducted under this protocol.

Approach:

A total of 105 children, aged 6.0 to 12.9 years, currently in treatment with psychotropic medications as outpatients at the mental health clinics of the study sites will be administered a basic demographic and clinical data form (Appendix A), with the General Inquiry Form (Appendix B) supplemented by the Drug Specific Inquiry Form (Appendix C) by a qualified clinical rater. These assessments will be immediately followed by a Systematic Inquiry Form (Appendix D), also administered to the patient and parent by a qualified clinical rater.

As a general rule, child and parent can be interviewed together. Based on individual circumstances, the rater can decide to further interview the child and/or the parent separately, as clinically indicated. Each child and her/his parent will contribute one interview to the study.

For a ‘qualified clinical rater’ it is here meant a clinician who, for education and training, can be considered competent in assessing children taking psychotropic medications. This category includes: child psychiatrists, psychiatrists, pediatricians, family doctors, and licensed nurses with advanced training in pediatrics and/or pediatrics. In addition, a ‘qualified clinical rater’ will have successfully gone through the specific training for this protocol in order to become familiar with the interview process and the scoring forms to be completed.

The same clinician will rate the same child/parent on both the ‘short’ and ‘long’ interview. The rater will inquire on the possible presence of AE since the last medication visit. The date of the last medication visit will be recorded. For each AE that is identified at any phase of the interview, the rater will collect information on its duration, severity, possible relationship with one or more medications the child is taking, and indicate whether the AE should prompt changes in clinical management of the child.
RUPP SAFETY EVALUATION STUDY: DEMOGRAPHICS

[ ] Columbia  [ ] NYU  [ ] Hopkins  [ ] Duke  [ ] UCLA  [ ] CWR

Case# ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Date Assessment Completed:

[ ] [ ] / [ ] / [ ] / [ ] / [ ] Namecode ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Staff ID: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Was any data collected for this form? (circle one) YES ☐ NO ☐ (If YES, continue)

A. RATER INFORMATION

1. Name of rater (person completing form)

2. Profession
   1 = pediatrician
   2 = child psychiatrist
   3 = general psychiatrist
   4 = nurse
   5 = other, specify:

3. Position
   1 = attending
   2 = resident
   3 = research fellow
   4 = other, specify:

4. How well does rater know this patient
   1 = no previous experience with this patient (new evaluation)
   2 = had one previous visit with this patient
   3 = had more than one previous visit with this patient

4a. If more than one previous visit, specify the number of prior visits

B. RECORD CURRENT TIME NOW

  __ __ : __ __ 1. Record current military time to the exact minute

C. SUBJECT DEMOGRAPHIC INFORMATION

1. Subject’s age at last birthday

  / / / __ __ __ __ 2. Date of birth

3a. Subject’s ethnicity
   1 = Hispanic or Latino
   2 = Not Hispanic or Latino

3b. Subject’s race
   1 = American Indian or Alaska Native
   2 = Asian
   3 = Black or African American
   4 = Native Hawaiian or Other Pacific Islander
   5 = White
   6 = Other (specify)

D. PHYSICAL EXAM

1. Subject’s height (inches)

2. Subject’s weight (pounds)

3. Blood pressure (after at least 3 minutes sitting)

   3a. Systolic (mmHg)
   3b. Diastolic (mmHg)

4. Pulse (bpm) (after at least 3 minutes sitting)

5. Were any lab tests ordered at this visit? (Yes=1, No=2)

5a. If you answered ‘Yes’ to question 5, specify

E. GENERAL FUNCTIONING

1. Overall functioning - Lowest level past week on CGAS scale

2. Current grade in school (if on summer vacation, last grade completed)

3. Is the child in a mainstream classroom? (Yes=1, No=2)

4. Does child receive special education services? (Yes=1, No=2)

4a. If yes, specify:

5. Overall academic performance (Enter number A=1, B=2, C=3, D=4)

6. Has the child ever had an IQ test? (Yes=1, No=2)

6a. If Yes, name of test

6b. Full scale score

6c. Date of test (Month / Year)
**F. MEDICATIONS**

1. Date of last medication visit
   
2. Has your child taken any medication since the last visit? (Yes=1, No=2)

*If yes, complete the table that spans these two pages*

3. **LIST ALL MEDICATIONS TAKEN SINCE THE LAST VISIT**
   (For psychotropic medication complete following section too)

<table>
<thead>
<tr>
<th>a. Drug Name</th>
<th>b. Purpose</th>
<th>c. Daily Dose</th>
<th>d. Units</th>
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<tr>
<td></td>
<td></td>
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<td>1=mg</td>
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<td>2=gms</td>
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<tr>
<th>e. Regimen</th>
<th>f. Route</th>
<th>g. Date Started</th>
<th>h. Date Stopped</th>
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<tbody>
<tr>
<td>1=QD</td>
<td>1=Oral</td>
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<tr>
<td>2=BID</td>
<td>2=Patch</td>
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<td>3=TID</td>
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<td>4=QID</td>
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<td>5=QHS</td>
<td>5=Spray</td>
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<td>7=Other</td>
<td>6=Other</td>
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<th>g. Date Started</th>
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G. RECORD CURRENT TIME NOW

1. Record current military time to the exact minute
PART 2. GENERAL INQUIRY

NOTE: if an adverse event is reported, please use terms (if applicable) on “LIST OF PREFERRED TERMS” when recording the event on the CRF (Part 5). The list comprises Part 7.

G. RECORD CURRENT TIME NOW

__ __ : __ __ Record current military time to the exact minute

G1.

I want to find out how [he/she] has been feeling since his/her last medication visit on [DATE]. For these questions I want you to think about all the time since DATE up until today.

Has ________ had any physical, emotional or behavioral problems during the time since [his/her] last visit …since NAME DATE? I’m talking about something that started to become a problem during this time or an old problem that got much worse.

IF YES: What kind of problem did [he/she] have?

_____ G1. Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering G1 for first field and complete the report. Then return here and go to next question.

Use this space for notes

G2.

Have there been activities that ________ didn’t do as often or that [he/she] didn’t do at all because of not feeling well since his/her visit on [DATE]?

IF YES: Tell me about this.

_____ G2. Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering G2 for first field and complete the report. Then return here and go to next question.

Use this space for notes
G3.

Since his/her last (medication) visit, has _____ said that [his/her] body feels funny…or that [he/she] has any aches or pains….or that some part of [him/her] hurts or doesn’t feel well?

IF YES: Tell me more about this.

_____ G3. Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering G3 for first field and complete the report. Then return here and go to next question.

Use this space for notes

G4.

Observe the patient’s appearance and behavior for such problems as above areas – e.g., skin irritation, weight gain or loss drowsiness, restlessness or inability to sit, trouble breathing, tremor, rigidity, and other abnormal movements and inquire about those not reported on previously:

I notice that (OBSERVED PROBLEM). Has that been bothering _____ or bothering you?

_____ G4. Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering G4 for first field and complete the report. Then return here and go to next question.

Use this space for notes

G5. RECORD CURRENT TIME NOW

___ ___ : ___ ___ Record current military time to the exact minute
ESSENTIAL INFORMATION
ON CURRENT MEDICATIONS

Please enter a “1” next to each class of Psychotropic Medications that were taken during period of assessment (since last medication visit). Then, for each psychotropic medication taken, complete follow-up questions in the MEDICATION SPECIFIC INQUIRY section indicated.

a. Stimulants: complete Section 3.1
b. SSRIs (fluoxetine, sertraline, paroxetine, fluvoxamine, citalopram), Venlafaxine (Effexor): complete section 3.2
c. Bupropion: complete section 3.3
d. Mirtazapine: complete section 3.4
e. Antipsychotics: complete Section 3.5
f. Benztrpine (trihexyphenidyl, diphenhydramine): complete section 3.6
g. Valproate, Depakote: complete section 3.7
h. Carbamazepine: complete section 3.8
i. Lithium: complete section 3.9
j. Clonidine, guanfacine: complete section 3.10
k. Lamotrigine: complete section 3.11
l. Topiramate: complete section 3.12
m. Tricyclic antidepressants (imipramine, clomipramine, desipramine, nortriptyline, amitriptyline, etc.): complete section 3.13
n. Benzodiazepines (diazepam, clonazepam, lorazepam, etc.) - sedation, disinhibition, seizures - (upon withdrawal): complete section 3.14
o. Neurontin: no medication specific checklist
p. Trazodone - priapism - FOR BOYS ONLY: complete section 3.15
q. Buspirone: no medication specific checklist
r. Nefazodone: complete section 3.16

Part 3: MEDICATION SPECIFIC INQUIRY
Before administering this part, the rater should refer to the list on Page 4 (final page of Part 1) to determine which sections to administer.

3. RECORD CURRENT TIME NOW
      : Record current military time to the exact minute

3.1. If subject has taken STIMULANTS since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

During (assessment period), has ______
- had any strange experiences, like hearing things that aren’t there or seeing things nobody else could see?
- been very sad or depressed for long periods of time?
- had a major problem sleeping (sleep delay of more than 2 hours)?
- taken more medication than [he/she] should have because [he/she] wanted to get “high?”

Hallucinations
Continuous dysphoria
Major sleep problem (delay of more than 2 hours)
Abuse of the medication

3.1 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.1 for first field and complete the report. Then return here and go to next question.
3.2. If subject has taken SSRIs (fluoxetine, sertraline, paroxetine, fluvoxamine, citalopram) OR VENLAFAXINE since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

During (assessment period), has ______
- been very grumpy or irritable, so that even little things would make him mad or set [him/her] off?
- had a major problem sleeping (sleep delay of more than 2 hours)?
- seemed very restless or keyed up…moving around a lot, like [he/she] had to keep moving around – a big change from how [he/she] usually is?
- have you noticed [his/her] hands trembling…or [his/her] body shaking a lot…
- acted like [his/her] thoughts were mixed up or seemed confused?
- had a fever or looked feverish? (Did you take [his/her] temperature? if applicable: what was it?)

Irritability
Major sleep problem (delay of more than 2 hours)
Hypomanic/manic mood
Agitation
Serotonergic syndrome (key symptoms are: tremor, myoclonus, fever, confusion, and restlessness)

IF subject has taken VENLAFAXINE since last medication visit -- BP should be measured.

Elevated BP

_____ 3.2 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.2 for first field and complete the report. Then return here and go to next question.

3.3. If subject has taken BUPROPRION since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

During (assessment period), has [he/she] lost consciousness…or had a seizure?

Seizures

_____ 3.3 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.3 for first field and complete the report. Then return here and go to next question.

3.4. If subject has taken MIRTAZAPINE since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

During (assessment period), has ______
- had a fever or looked feverish? (Did you take [his/her] temperature? if applicable: what was it?)
- had any sort of infection?
- seemed very sluggish or has [he/she] looked or complained about "feeling drugged" or has [he/she] looked “out of it” or seemed much less alert than usual?
- gained a lot of weight?
- had any sort of infection?
- seemed very sluggish or has [he/she] looked or complained about "feeling drugged" or has [he/she] looked “out of it” or seemed much less alert than usual?
- gained a lot of weight?

Fever
Infection
Sedation
Major weight gain (at least 10 lb in a month).

_____ 3.4 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.4 for first field and complete the report. Then return here and go to next question.
3.5. If subject has taken **ANTIPSYCHOTICS** (since last medication visit, **ASK**:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

During (assessment period), has ______
- had a fever or looked feverish? (Did you take [his/her] temperature? if applicable: what was it?)
- had any strange or unusual body or muscle movements, like:
  - moving around really slowly in a snake-like movement again and again
  - holding [his/her] jaw in a strange way or clenching it
  - moving [his/her] mouth or tongue too much or in a strange way
  - [his/her] body or some part of [his/her] body freezing in a certain odd position
  - [his/her] eyes rolling back in [his/her] head
  - anything else where [his/her] muscles were all tightened up and it was hard to relax them?
- seemed or complained about being very stiff or rigid?
- gained a lot of weight?

Fever
Dyskinesias
Dystonias
Rigidity
Major weight gain (at least 10 lb in a month)

_____ 3.5a Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.5a for first field and complete the report. Then return here and go to next question.

If subject has taken **CLOZAPINE** since last medication visit **OBTAIN** WBC (if necessary – see below) AND ask the following additional questions:

- complained of feeling dizzy or like [he/she] might faint?
- had any infections?
- had a blood count done?

Seizures
Dizziness
Infections
Drop in WBC (defined by at least one of the following: single drop of 3,000 or more in WBC, WBC below 3,500, or absolute neutrophil count below 1,500: inquire about when latest WBC and absolute neutrophil count was done and what the values were)

_____ 3.5b Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.5b for first field and complete the report. Then return here and go to next question.

If subject has taken **PIMOZIDE, ZIPRASIDONE** since last medication visit, **ASK**:

- said that [his/her] heart was beating too fast…or too hard?
- complained about pain or discomfort in [his/her] chest?

Palpitations
Chest pain, [inquire when latest EKG was obtained and record date and if there were abnormal results]

_____ 3.5c Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.5c for first field and complete the report. Then return here and go to next question.
3.6. If subject has taken **BENZTROPINE, TRIHEXYPHENIDYL, DIPHENHYDRAMINE** since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

During (assessment period), has ______
- seemed very sluggish or has [he/she] looked or complained about “feeling drugged” or has [he/she] looked “out of it” or seemed much less alert than usual?
- acted like [his/her] thoughts were mixed up or seemed confused?

Sedation
Confusion

_____ 3.6 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to **SMURF AE Report** entering 3.6 for first field and complete the report. Then return here and go to next question.

3.7. If subject has taken **VALPROATE** since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

During (assessment period), has ______
- complained of stomach aches or belly aches?
- been sick to [his/her] stomach...so that [he/she] vomited?
- been bruising very easily or bleeding very easily?

Abdominal pain
Vomiting
Easy bruising/bleeding

_____ 3.7 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to **SMURF AE Report** entering 3.7 for first field and complete the report. Then return here and go to next question.
3.8. If subject has taken **CARBAMAZEPINE** since last medication visit, ASK:

*Since the last medication visit on [DATE], _____ [has been taking/took] [NAME MEDICATION].*

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

**During (assessment period), has _____**
- had a fever or looked feverish? *(Did you take [his/her] temperature? if applicable: what was it?)*
- had any sort of infection?
- been bruising very easily or bleeding very easily?
- had a blood count done?

Fever
Infections
Easy bruising/bleeding
Drop in WBC (defined by at least one of the following: single drop of 3,000 or more in WBC, WBC below 3,500, or absolute neutrophil count below 1,500: inquire about when latest WBC and absolute neutrophil count was done and what the values were)

_____ **3.8 Was a problem detected?**
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to **SMURF AE Report** entering 3.8 for first field and complete the report. Then return here and go to next question.

3.9. If subject has taken **LITHIUM** since last medication visit, ASK:

*Since the last medication visit on [DATE], _____ [has been taking/took] [NAME MEDICATION].*

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

**During (assessment period), has _____**
- had a problem with pimples or with acne – either [he/she] got acne for the first time or the acne [he/she] already had got much worse
- been sick to [his/her] stomach...so that [he/she] vomited?
- had diarrhea so that [he/she] spent a lot of time in the bathroom?
- seemed much more clumsy than [he/she] usually is?
- complained of feeling weak...like [his/her] muscles were much weaker than usual?
- acted like [his/her] thoughts were mixed up or seemed confused?
  [inquire about most recent serum level and record date of sampling and Li level]

Acne
Vomiting
Diarrhea
Motor uncoordination
Muscle weakness
Confusion

_____ **3.9 Was a problem detected?**
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to **SMURF AE Report** entering 3.9 for first field and complete the report. Then return here and go to next question.
3.10. If subject has taken **CLONIDINE, GUANFACINE** since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

During (assessment period), has ______
- seemed very sluggish or has [he/she] looked or complained about “feeling drugged” or has [he/she] looked “out of it” or seemed much less alert than usual?
- complained of feeling dizzy or like [he/she] might faint?
- said that [his/her] heart was beating too fast…or too hard?

Now I want you to think about when [he/she] didn’t take [his/her] medication or when it was time to take it again. At that time:
- would [he/she] seem very nervous… or keyed up?
- would [he/she] get headaches?
- would [he/she] seem shaky or tremble?

Sedation
Dizziness
Palpitations
Possible symptoms of withdrawal (nervousness, agitation, headache, tremor)

_____ 3.10 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to **SMURF AE Report** entering 3.10 for first field and complete the report. Then return here and go to next question.

3.11. If subject has taken **LAMOTRIGINE** since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

During (assessment period), has [he/she] had any skin irritation or rashes?

Rash

_____ 3.11 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to **SMURF AE Report** entering 3.11 for first field and complete the report. Then return here and go to next question.

3.12. If subject has taken **TOPIRAMATE** since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

During (assessment period), has it seemed like [his/her] thinking was slowed down?

Slow thinking

_____ 3.12 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to **SMURF AE Report** entering 3.12 for first field and complete the report. Then return here and go to next question.
3.13. If subject has taken TRICYCLIC ANTIDEPRESSANTS (IMIPRAMINE, CLOMIPRAMINE, DESIPRAMINE, NORTRIPTYLINE, AMITRIPTYLNE, etc.) since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

During (assessment period), has ______
- complained of feeling dizzy or like [he/she] might faint?
- said that [his/her] heart was beating too fast…or too hard?
- complained about pain or discomfort in [his/her] chest?

Dizziness
Palpitations
Chest pain, [inquire when latest EKG was obtained and record date and if there were abnormal results]

_____ 3.13 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.13 for first field and complete the report. Then return here and go to next question.

3.14. If subject has taken BENZODIAZEPINES (DIAZEPAM, CLONAZEPAN, LORAZEPAN, etc.) since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

Now I want to ask you some questions about possible side effects he/she may have had from this medicine.

During (assessment period), has ______
- seemed very sluggish or has [he/she] looked or complained about “feeling drugged” or has [he/she] looked “out of it” or seemed much less alert than usual?
- acted much different than [he/she] usually does, sort of like [he/she] has lost [his/her] “stop signal”…that is [he/she] does things like interrupting people a lot more than is normal for [him/her] …or being much louder than [he/she] usually is or much more talkative…or being overly friendly to people [he/she] normally wouldn’t have spoken to … or something like that? I’m talking about something that is a big change for [him/her].
- lost consciousness…or had a seizure?
- [his/her] behavior or mood changed very suddenly in a bad way…like [he/she] is acting like a different person or [he/she] does things you’ve never seen before?

Sedation
Disinhibition
Seizures (upon withdrawal)
Subsyndromal “seizures”

_____ 3.14 Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.14 for first field and complete the report. Then return here and go to next question.
3.15. If subject is MALE and has taken TRAZODONE since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

During (assessment period), have you noticed or has he told you that his penis was always hard…that he had an erection most of the time?

Priapism

_____ 3.15 Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.15 for first field and complete the report. Then return here and go to next question.

3.16. If subject has taken NEFAZODONE since last medication visit, ASK:

Since the last medication visit on [DATE], ______ [has been taking/took] [NAME MEDICATION].

During (assessment period), have you noticed that [his/her] skin or eyes are yellow, urine is dark, very tired, feeling bloated in the belly, loss of appetite, or ,FOR BOYS ONLY, has he told you that his penis was always hard…that he had an erection most of the time?

Tiredness/fatigue
Change in urine color
Appetite decrease
Priapism

_____ 3.16 Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 3.16 for first field and complete the report. Then return here and go to next question.

Enter the Names of any Laboratory Tests Ordered as a result of the Inquiries for Items 3.1 through 3.16

Test #1

Test #2

Test #3

Test #4

Test #5

Test #6

Test #7

Test #8

Test #9

Test #10

Test #11

Test #12
PART 4: CLINICIAN SATISFACTION RATINGS

Note: Please give the Parent Satisfaction Rating Form 1 to the parent to complete along with an envelope into which the parent can put the form. Tell the parent to place the form in the envelope, seal the envelope, and give it to you to return to the researchers. While the parent is completing the form, you should answer the following questions.

4. RECORD CURRENT TIME NOW

_ _ : _ _ Record current military time to the exact minute

Please answer all the questions below based on your impression of the interview so far. For each question please enter the number of the response that best expresses how you honestly feel.

____ 4.1 How useful was this interview as a whole for the purpose of checking whether the patient is having some unwanted side effects from the medication [he/she] is taking?
1 - very useful
2 - somewhat useful
3 - not at all useful

____ 4.2 How do you judge the level of detail of the interview?
1 - not detailed enough, failed to ask about important information
2 - the level of detail was just right
3 - the was too much detail; too many unnecessary questions

____ 4.3 What do you think of the length (duration) of the interview?
1 - too long
2 - just right
3 - too short

____ 4.4 How easy was it to conduct the interview? For instance, were you able to get the needed full and continuous attention of the parent in order to get the information?
1 - easy, no problems
2 - fairly easy
3 - difficult: poor attention and motivation

____ 4.5 Was the parent able to understand the intent and meaning of the questions?
1 - yes, no problems
2 - parent found some of the questions a little difficult
3 - parent had much difficulty understanding the probes as written

____ 4.6 Would you be willing to make this interview part of all future visits to monitor this child's medication?
1 - definitely yes
2 - probably yes
3 - probably no
4 - definitely no
PART 5:
SPECIFIC INQUIRY BY DIFFERENT “BODY SYSTEMS”

5. RECORD CURRENT TIME NOW
__ __ : __ __  Record current military time to the exact minute

Now I’d like to ask you some more specific questions about ______’s health during the time since [his/her] last (medication) visit, that is since [INSERT DATE].

A. During the time since _____’s last (medication) visit, has [he/she] had any problems with [his/her] eyes or with how well [he/she] sees? By problems with [his/her] eyes, I mean things like [his/her] eyes getting red or irritated or swollen…[his/her] eyes being dry or watery… not being able to see as well or as clearly as usual…. complaining that light bothered [his/her] eyes a lot…seeing things like lights or specks that came and went…an eyelid twitch?

Has [he/she] had any problems like that?
What was the problem?

Eye irritation
Dry or watery eyes
Blurred or poor vision
Double vision
Light bothering eyes
Perceptual problems
Eyelid twitch (blepharospasm)
Other problem(s) with EYES,
SPECIFY: __________________________

_____ 5.A  Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.A for first field and complete the report. Then return here and go to next question.

B. During (assessment period) has [he/she] had any trouble with [his/her] ears or with hearing … things like pain or discharge or feeling like [his/her] ears were clogged up…trouble hearing things…buzzing or ringing in [his/her] ears?

Ear ache
Ear infection
Poor hearing
Ringing in the ears
Other problem(s) with EARS,
SPECIFY: __________________________

_____ 5.B  Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.B for first field and complete the report. Then return here and go to next question.

C. During (assessment period) has ____ had problems with [his/her] head or with [his/her] face? By this I mean things like headaches…or feeling pain on [his/her] face….a muscle in [his/her] face being weak

Headache
Facial pain
Face muscle weakness
Other problem(s) with “HEAD,” or “FACE”
SPECIFY: __________________________

_____ 5.C  Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.C for first field and complete the report. Then return here and go to next question.
D. During (assessment period), has ___ had any problems with [his/her] nose or with [his/her] sinuses or with [his/her] throat?

I'm talking about things like nose bleeds, [his/her] nose feeling very dried out, stuffy nose, increased or decreased sense of smell, pain behind [his/he] eyes, sore throat, being very hoarse or having laryngitis, difficulty swallowing or other things like that.

Has [he/she] had any problems like that?

- Nose bleeds
- Nasal dryness
- Nasal/sinus congestion
- Increased sense of smell
- Decreased sense of smell
- Sore throat
- Hoarse voice/Laryngitis
- Difficulty swallowing
- Other problem(s) with NOSE/SINUSES/THROAT, SPECIFY:

_____ 5.D  Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.D for first field and complete the report. Then return here and go to next question.

E. During (assessment period) has _____ had any problems with [his/her] mouth or lips or teeth… things like sores in or on [his/her] mouth, bleeding or swollen gums… dental problems…swollen or sore tongue…[his/her] mouth feeling very dry …or having too much saliva in [his/her] mouth or drooling…or having a bad taste in [his/her] mouth?

- Mouth ulcer/canker sore
- Gum problems
- Dental problems
- Sore/swollen tongue
- Dry mouth
- Hypersalivation (too much saliva)
- Drooling
- Bad taste in mouth
- Other problem(s) with MOUTH/LIPS/TEETH, SPECIFY: _________________

_____ 5.E  Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.E for first field and complete the report. Then return here and go to next question.
F. During (assessment period) has ___ had any problems with [his/her] chest or with [his/her] breathing?

I'm talking about things like having pains in [his/her] chest…[his/her] chest feeling tight or uncomfortable…being short of breath…noisy breathing or wheezing…coughing a lot…and so on? Has [he/she] had any problems like that?

Chest pain
Chest tightness
Shortness of breath
Wheezing
Coughing
Other problem(s) with CHEST,
SPECIFY: __________________________________________________________

5.F. Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.F for first field and complete the report. Then return here and go to next question.

G. During (assessment period) has ___ had any problems with [his/her] breasts, such as [his/her] breasts being swollen or having pain in [his/her] breasts… or any discharge from [his/her] nipples?

Breast swelling
Breast pain
Discharge (nipples)
Other problem(s) with BREASTS,
SPECIFY: __________________________________________________________

5.G. Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.G for first field and complete the report. Then return here and go to next question.

H. During (assessment period) has ____ had any trouble with [his/her] heart…. …such as it beating too fast or pounding…or skipping beats…or [his/her] heart beating too slowly?

Rapid heartbeat
Irregular heartbeat (skips beat)
Slow heartbeat
Other problem(s) with HEART,
SPECIFY: __________________________________________________________

5.H. Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.H for first field and complete the report. Then return here and go to next question.
I. During (assessment period) has [he/she] had any problems with [his/her] stomach or belly...that is, any aches or pains or cramps...any heartburn...any nausea, or vomiting?

- Pain/discomfort
- Heartburn/reflux
- Nausea
- Vomiting
- Other problem(s) with STOMACH/BELLY,
  SPECIFY: ____________________________________________

_____ 5.I Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.I for first field and complete the report. Then return here and go to next question.

J. During (assessment period), has [he/she] had any problems with [his/her] bowels....I'm talking about things like diarrhea or very loose stools...being constipated or having trouble moving [his/her] bowels or painful bowel movements...blood in [his/her] stools...having a lot of gas or farting a lot...[his/her] bowel movements being a funny color ...or smelling very different than is usual...any problems with hemorrhoids or bleeding?

- Diarrhea
- Constipation
- Blood in stools
- Flatulence, bloated, gassy
- Stool discoloration
- Hemorrhoids
- Other problem(s) with BOWELS,
  SPECIFY: ____________________________________________

_____ 5.J Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.J for first field and complete the report. Then return here and go to next question.

K. During (assessment period) has [he/she] had any problems with [his/her] appetite or with eating? I'm talking about things like being much hungrier than usual or wanting to eat a lot more....having no appetite at all or not wanting to eat....gaining or losing any weight....food tasting differently... being very thirsty?

- Appetite increase
- Appetite decrease
- Weight gain
- Weight loss
- Taste abnormality
- Increased thirst
- Other problem(s) with APPETITE/EATING,
  SPECIFY: ____________________________________________

_____ 5.K Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.K for first field and complete the report. Then return here and go to next question.
L. During (assessment period) has _____ had any problems with urinating or peeing…. things like pain or burning when [he/she] pees…. difficulty with starting to pee or urinate… decrease in how fast the urine or pee comes out or in how much comes out… needing to pee or urinate more often… a change in the color of [his/her] urine… or in how [his/her] pee smells?

Has he/she had problems holding [his/her] urine or pee so that [he/she] has wet [himself/herself] or wet [his/her] bed? (Is that a change from usual?)

Painful urination
Difficulty urinating
Increased frequency (urination)
Change in urine color
Change in urine smell
Daytime wetting (diurnal enuresis)
Bedwetting (nocturnal enuresis)
Other problems with URINATION,
SPECIFY: ____________________________________________

_____ 5.L Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.L for first field and complete the report. Then return here and go to next question.

M. (FOR FEMALES): When did her last menstrual period start?
Month/ Day: _____/_____

During (assessment period) has she had any problems with menstruation or with her menstrual cycle. I’m talking about things like not getting her period when she expected it… having very bad cramps… having much heavier bleeding than is usual for her… spotting between her periods…. pain between her period… being unusually moody or irritable right before she menstruates or within the first day or so… or anything like that.

Menstrual irregularity
Cramps
Increased bleeding
"Breakthrough" bleeding/spotting
Midcycle pain
Premenstrual tension or mood change
Other problem(s) with MENSTRUATION,
SPECIFY: ____________________________________________

_____ 5.M Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.M for first field and complete the report. Then return here and go to next question.

______________________________________________________
N. During (assessment period) has [he/she] had any problems with [his/her] genitals or private parts? I'm talking about things like any pain or swelling…discharge…or (if applicable) any changes in how interested [he/she] is in sex…or any problems with sex?

   Genital discomfort/swelling
   Genital discharge
   Increased sexual urges/interest (increased libido)
   Decreased sexual urges/interest (decreased libido)
   Sexual dysfunction
   Other problems with GENITALS/SEX,
   SPECIFY: ________________________________

_____ 5.N Was a problem detected?
   1=No. Go to next question.
   2=Yes, but previously reported. Go to the next question.
   3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.N for first field and complete the report. Then return here and go to next question.

O. During (assessment period) has ____ had any problems with [his/her] muscles, [his/her] bones, or [his/her] joints? I mean things such as aches or pains…leg cramps…swelling in [his/her] arms and legs…tingling or numbness in [his/her] hands or feet…[his/her] legs feeling very restless like it was hard to keep them still?

   Muscle/bone/joint pain
   specify where: ________________________________
   Edema/swelling
   specify where: ________________________________
   Cramps/muscle contractions
   specify where: ________________________________
   Numbness or tingling in arms or legs
   Restless legs
   Other problem(s) with MUSCLES, BONES, JOINTS,
   SPECIFY: ________________________________

_____ 5.O Was a problem detected?
   1=No. Go to next question.
   2=Yes, but previously reported. Go to the next question.
   3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.O for first field and complete the report. Then return here and go to next question.

P. During (assessment period) has ____ had any problems with the way [he/she] walks or moves? I'm talking about things like being very clumsy or unsteady on [his/her] feet…trouble controlling unwanted movements or having sudden jerky movements that are hard for [him/her] to control…feeling very restless or like [he/she] couldn't keep from moving…trembling or shaking…trouble starting to move…or feeling stiff or rigid?

   Clumsiness/disturbance of coordination
   Dyskinesia
   Specify where: ________________________________
   Tics
   describe: ________________________________
   Akathisia (urge to move)
   Tremor, trembling or shaking
   Rigidity (muscle), aches, cramps
   Other problems with MOVEMENT,
   SPECIFY: ________________________________

_____ 5.P Was a problem detected?
   1=No. Go to next question.
   2=Yes, but previously reported. Go to the next question.
   3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.P for first field and complete the report. Then return here and go to next question.
Q. During (assessment period) has [he/she] had any problems with [his/her] skin, hair, or scalp… things like rashes or itching or irritation… having a lot more pimples than usual or breaking out… breaking out in hives… having skin blisters, not caused from any kind of friction or rubbing… [his/her] skin or hair being very dry… flaking scalp… [his/her] skin being much more sensitive to the sun… or [his/her] skin looking different, like it’s a different color than usual… Or has [his/her] skin or hair been much more oily than usual… or has [he/she] been sweating a lot… or has [he/she] smelled different than usual… or has [his/her] hair been very brittle or fallen out more than usual?

Has [he/she] got a lot of bruises … more than usual?

- Rashes or Skin irritation
- Pimples or acne
- Hives or urticaria
- Skin blisters (other than from friction)
- Dry skin
- Flaking scalp
- Skin sensitivity to sun
- Oily skin or hair
- Excess sweating
- Change in body odor
- Hair problems (loss, brittle)
- Easy bruising

specify where: ______________________________________

Other problem(s) with SKIN/HAIR/SCALP, SPECIFY: ______________________________________

_____ 5.Q  Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.Q for first field and complete the report. Then return here and go to next question.

R. During (assessment period) have there been any problems with [his/her] energy level? For example, has [he/she] had less energy than usual or seemed very tired or worn out? Has [he/she] complained of “feeling drugged” or looked “out of it” or has [he/she] seemed much less alert than usual? Does [he/she] seem more withdrawn … or just stare into space? Does [he/she] yawn a lot? Or how about the opposite: has [he/she] had too much energy or seemed too excited or overactive? Has it seemed like [he/she] was too keyed up and couldn’t settle down?

- Tiredness/fatigue
- Sedation/drugged feelings
- Withdrawn
- Staring
- Excessive yawning
- Overly excited or energetic
- Too keyed up/Unable to settle down

Other problem(s) with ENERGY, SPECIFY: ______________________________________

_____ 5.R  Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.R for first field and complete the report. Then return here and go to next question.
S. During (assessment period), has ____ any sleep problems? By this I mean any problems falling asleep, staying asleep, waking up too early, sleeping too much or feeling drowsy during the day? Did it seem like the sleep that [he/she] did get wasn’t making [him/her] feel rested? How about nightmares or strange dreams?

- Difficulty falling asleep
- Interrupted sleep
- Early morning awakening
- Sleeping too much
- Non restorative help
- Drowsiness
- Nightmares, strange dreams
- Other problem(s) with SLEEP, SPECIFY:

_____ 5.S Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.S for first field and complete the report. Then return here and go to next question.

T. During (assessment period), has ____ had any strange experiences or strange ideas or thoughts? By this I mean things like seeing things that other people couldn’t see …or having visions …or hearing things that other people couldn’t hear……like voices or smelling things that nobody else could smell… or having a bad taste in [his/her] mouth that wasn’t caused by anything …or feeling like someone was touching [him/her] when nothing was there or having unusual feelings inside [his/her] body like something was moving inside …or any ideas that were very strange or didn’t make sense, so that you thought there was something seriously wrong with him/her.

- Seeing things that are not there (visual hallucinations)
- Hearing things that are not there (auditory hallucinations)
- Smelling or tasting things that are not there (olfactory hallucinations)
- Strange physical feelings (tactile hallucinations)
- Strange thoughts
- Other STRANGE EXPERIENCES OR THOUGHTS, SPECIFY:

_____ 5.T Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.T for first field and complete the report. Then return here and go to next question.
U. During (assessment period) any (other) problems with how [he/she] thinks? I mean a real change from usual. For example, has [he/she] been more forgetful than usual or had more problems remembering things… or has [he/she] had problems concentrating on things… or has [he/she] seemed confused or like he/she wasn’t thinking clearly… or has it seemed like [he/she] was thinking more slowly than usual or that [he/she] had problems finding words or speak more slowly or less clearly? Has [he/she] felt dizzy or like [he/she] might pass out or might faint? During (assessment period) has [he/she] lost consciousness or had a seizure?

- Memory problems
- Concentration difficulty
- Confusion
- Slowed thinking
- Speech disturbances/changes, SPECIFY:

Other problem(s) with THINKING, SPECIFY: 

- Dizziness/faintness
- Loss of consciousness

5.5. Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.U for first field and complete the report. Then return here and go to next question.

V. During (assessment period) has ___ had any problems with [his/her] mood or with [his/her] spirits… such as feeling sad or down or depressed… feeling worried or anxious or nervous… being very bored and unable to be interested in anything… being very angry or irritable… or being much too hyped up and excited?

- Depression
- Anxiety/nervousness
- Loss of interest/motivation
- Irritability
- “Hypomanic/manic” mood
- Other problem(s) with MOOD, SPECIFY: 

5.5. Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.V for first field and complete the report. Then return here and go to next question.

W. Since his/her last (medication) visit, has ____ had an accident or emergency that made [him/her] go see a doctor or other medical professional or go to a hospital?

- Accidental injury
- Attempted suicide
- Medical or Surgical Procedure
- Medicine,

SPECIFY what and why:

5.5. Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.W for first field and complete the report. Then return here and go to next question.
X. Since his/her last (medication) visit, has ____ been sick with a fever or had any kind of illness like a cold or the 'flu'? (What was wrong with [him/her]? Did you take [his/her] temperature? If applicable: what was it?)

Has [he/she] had any sort of allergies or allergic reactions or an asthma attack?
Has [he/she] had swollen glands or lumps in his/her neck area?
Has [he/she] said that [he/she] felt too warm or did [he/she] look flushed?
Has [he/she] said that [he/she] feel very cold or that [he/she] had chills?

Upper respiratory infection
Lower respiratory infection
Gastro-intestinal virus
Bacterial infection
Urinary tract infection
(Other) fever
Allergies/asthma
Swollen glands or lymph nodes (Lymphadenopathy)
Feeling flushed or warm
Feeling cold or chilled
Other intercurrent illness,
SPECIFY: ________________________________

___ 5.X. Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.X for first field and complete the report. Then return here and go to next question.

CLOSING INQUIRY

Observe the patient’s appearance and behavior for such problems as above areas – e.g., skin irritation, weight gain or loss drowsiness, restlessness or inability to sit, trouble breathing, tremor, rigidity, and other abnormal movements and inquire about those not reported on previously:

Y. I notice that (OBSERVED PROBLEM). Has that been bothering ____ or bothering you?

___ 5.Y Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.Y for first field and complete the report. Then return here and go to next question.

If the informant fails to mention a problem that has been observed by the patient or other family member ask Z

Z. (FAMILY MEMBER) mentioned that (MENTIONED PROBLEM). Has that been bothering ____ or bothering you?

___ 5.Z Was a problem detected?
1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.Z for first field and complete the report. Then return here and go to next question.
Follow up on any problem reported in previous visits that was not mentioned at this interview by the family or patient.

**AA.** Last time (REPORTED PROBLEM) was bothering _____. Is [he/she] still having trouble with that?

_____ **5.AA** Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.AA for first field and complete the report. Then return here and go to next question.

Enter the Names of any Laboratory Tests Ordered as a result of the Inquiries for Items 5.A through 5.BB

<table>
<thead>
<tr>
<th>Test #1</th>
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<td>Test #2</td>
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<td>Test #12</td>
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**BB.** Lastly, has your medicine caused ____ any problems during the past week (or specified interval) that we haven’t talked about?

_____ **5.BB** Was a problem detected?

1=No. Go to next question.
2=Yes, but previously reported. Go to the next question.
3=Yes, possible or definite AE. Go to SMURF AE Report entering 5.BB for first field and complete the report. Then return here and go to next question.
PART 6: CLINICIAN SATISFACTION RATINGS

Note: Please give the Parent Satisfaction Rating Form 2 to the parent to complete along with an envelope into which the parent can put the form. Tell the parent to place the form in the envelope, seal the envelope, and give it to you to return to the researchers. While the parent is completing the form, you should answer the following questions.

6. RECORD CURRENT TIME NOW

__ __ : __ __ Record current military time to the exact minute

Please answer all the questions below based on your impression of the interview. For each question please enter the number of the response that best expresses how you honestly feel.

_____ 6.1 How useful was this interview as a whole for the purpose of checking whether the patient is having some unwanted side effects from the medication [he/she] is taking?
1 - very useful
2 - somewhat useful
3 - not at all useful

_____ 6.2 How do you judge the level of detail of the interview?
1 - not detailed enough, failed to ask about important information
2 - the level of detail was just right
3 - there was too much detail; too many unnecessary questions

_____ 6.3 What do you think of the length (duration) of the interview?
1 - too long
2 - just right
3 - too short

_____ 6.4 How easy was it to conduct the interview? For instance, were you able to get the needed full and continuous attention of the parent in order to get the information?
1 - easy, no problems
2 - fairly easy
3 - difficult: poor attention and motivation

_____ 6.5 Was the parent able to understand the intent and meaning of the questions?
1 - yes, no problems
2 - parent found some of the questions a little difficult
3 - parent had much difficulty understanding the probes as written

_____ 6.6 Would you be willing to make this interview part of all future visits to monitor this child’s medication?
1 - definitely yes
2 - probably yes
3 - probably no
4 - definitely no
PART 7. LIST OF PREFERRED TERMS

NOTE: These terms should be used (whenever possible) when completing the SMURF AE Reporting form, the CRF.

EYES
- Eye irritation
- Dry or watery eyes
- Blurred or poor vision
- Double vision
- Light bothering eyes
- Perceptual problems
- Eyelid twitch (blepharospasm)
- Other problem(s) with EYES, SPECIFY

EARS
- Ear ache
- Ear infection
- Poor hearing
- Ringing in the ears
- Other problem(s) with EARS, SPECIFY:

HEAD, FACE
- Headache
- Facial pain
- Face muscle weakness
- Other problem(s) with “HEAD,” or “FACE” SPECIFY:

NOSE, SINUS, THROAT
- Nose bleeds
- Nasal dryness
- Nasal/sinus congestion
- Increased sense of smell
- Decreased sense of smell
- Sore throat
- Hoarse voice/Laryngitis
- Difficulty swallowing
- Other problem(s) with NOSE/SINUSES/THROAT, SPECIFY:

MOUTH, LIPS, TEETH
- Mouth ulcer/canker sore
- Gun problems
- Dental problems
- Sore/swollen tongue
- Dry mouth
- Hypersalivation (too much saliva)
- Drooling
- Bad taste in mouth
- Other problem(s) with MOUTH/LIPS/TEETH, SPECIFY:

CHEST, BREATHING, BREASTS
- Chest pain
- Chest tightness
- Shortness of breath
- Wheezing
- Coughing
- Other problem(s) with CHEST, SPECIFY:
- Breast swelling
- Breast pain
- Discharge (nipples)
- Other problem(s) with BREASTS, SPECIFY:

HEART
- Rapid heartbeat
- Irregular heartbeat (skips beat)
- Slow heartbeat
- Other problem(s) with HEART, SPECIFY:
GASTROINTESTINAL, APPETITE, EATING, TASTE etc

GASTROINTESTINAL, APPETITE, EATING, TASTE etc

Stomach pain/discomfort
Heartburn/reflux
Nausea
Vomiting
Other problem(s) with STOMACH/BELLY,
SPECIFY: ________________________________

Diarrhea
Constipation
Blood in stools
Flatulence, bloated, gassy
Stool discoloration
Hemorrhoids
Other problem(s) with BOWELS,
SPECIFY: ________________________________

Appetite increase
Appetite decrease
Weight gain
Weight loss
Taste abnormality
Increased thirst
Other problem(s) with APPETITE/EATING,
SPECIFY: ________________________________

GENITOURINARY, URINARY

Painful urination
Difficulty urinating
Increased frequency (urination)
Change in urine color
Change in urine smell
Daytime wetting (diurnal enuresis)
Bedwetting (nocturnal enuresis)
Other problems with URINATION,
SPECIFY: ________________________________

Menstrual irregularity
Cramps
Increased bleeding
“Breakthrough” bleeding/spotting
Midcycle pain
Premenstrual tension or mood change
Other problem(s) with MENSTRUATION,
SPECIFY: ________________________________

SKIN, HAIR, SCALP

Rashes or Skin irritation
Pimples or acne
Hives or urticaria
Skin blisters (other than from friction)
Dry skin
Flaking scalp
Skin sensitivity to sun
Oily skin or hair
Excess sweating
Change in body odor
Hair problems (loss, brittle)
Easy bruising
specify where:
Other problem(s) with SKIN/HAIR/SCALP,
SPECIFY: ________________________________

MUSCULOSKETAL, MOVEMENT

Muscle/bone/joint pain
specify where:

Edema/swelling
specify where:

Cramps/muscle contractions
specify where:

Numbness or tingling in arms or legs
Restless legs
Other problem(s) with MUSCLES, BONES, JOINTS,
SPECIFY: ________________________________

Clumsiness/disturbance of coordination
Dyskinesia
specify where:

Tics
describe:

Akathisia (urge to move)
Tremor, trembling or shaking
Rigidity (muscle), aches, cramps
Other problems with MOVEMENT,
SPECIFY: ________________________________

SKIN, HAIR, SCALP

Rashes or Skin irritation
Pimples or acne
Hives or urticaria
Skin blisters (other than from friction)
Dry skin
Flaking scalp
Skin sensitivity to sun
Oily skin or hair
Excess sweating
Change in body odor
Hair problems (loss, brittle)
Easy bruising
specify where:
Other problem(s) with SKIN/HAIR/SCALP,
SPECIFY: ________________________________
ENERGY LEVEL
- Tiredness/fatigue
- Sedation/drugged feelings
- Withdrawn
- Staring
- Excessive yawning
- Overly excited or energetic
- Too keyed up/Unable to settle down
Other problem(s) with ENERGY,
SPECIFY: _______________________________

SLEEP
- Difficulty falling asleep
- Interrupted sleep
- Early morning awakening
- Sleeping too much
- Non restorative help
- Drowsiness
- Nightmares, strange dreams
Other problem(s) with SLEEP,
SPECIFY: _______________________________

PERCEPTUAL AND PSYCHOLOGICAL SYMPTOMS
- Seeing things that are not there (visual hallucinations)
- Hearing things that are not there (auditory hallucinations)
- Smelling or tasting things that are not there (olfactory hallucinations)
- Strange physical feelings (tactile hallucinations)
- Strange thoughts
Other STRANGE EXPERIENCES OR THOUGHTS,
SPECIFY: _______________________________

Memory problems
- Concentration difficulty
- Confusion
- Slowed thinking
- Speech disturbances/changes,
SPECIFY: _______________________________
Other problem(s) with THINKING,
SPECIFY: _______________________________
- Dizziness/faintness
- Loss of consciousness
- Depression
- Anxiety/nervousness
- Loss of interest/motivation
- Irritability
- “Hypomanic/manic” mood
Other problem(s) with MOOD,
SPECIFY: _______________________________

OTHER – ACCIDENTS/EMERGENCIES/ILLNESSES, INFECTIONS ETC.
- Accidental injury
- Attempted suicide
- Medical or Surgical Procedure
- Medicine,
  SPECIFY what and why: _______________________________
- Upper respiratory infection
- Lower respiratory infection
- Gastro-intestinal virus
- Bacterial infection
- Urinary tract infection
- (Other) fever
- Allergies/asthma
- Swollen glands or lymph nodes (Lymphadenopathy)
- Feeling flushed or warm
- Feeling cold or chilled
- Other intercurrent illness,
SPECIFY: _______________________________
<table>
<thead>
<tr>
<th>Staff ID:</th>
<th>Was any data collected for this form? (circle one)</th>
<th>YES</th>
<th>NO</th>
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1. Clinician Interview Script item being commented on: i.e., 3.12 or 5.G, etc., or ‘General’ for a global comment.

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