Daniel G. Shapiro, M.D. Developmental and Behavioral Pediatrics 11705 Magruder Lane Rockville, Maryland 20852 Telephone: 301-881-6855 Fax: 301-881-9849

NEUROLEPTIC MEDICATION TRIAL

Child's name:

Grade:

Relation to child:

Year:

Person completing this form: _

Dear Parents, Teachers, and Student:

Thank you very much for your help. It is so important to conduct this medication trial in a careful and controlled fashion. Please complete the table below. Your comments in narrative form are also very helpful. On the back, please record the date and describe the following: If there were side effects, at what time did you usually notice this? Do medicine benefits seem to "kick-in" too late or "wear off" too early? General comments about side effects. General comments about benefits. Please call me if you have any questions or concerns. Thank you.

How often did you notice the following? 0=not at all, 1=just a little, 2=often, 3=very often

DOSE					
DOSETARGET SYMPTOMSDATE	 	 	 	 	 $\left \right $
Restless, manic, hyper, "on-the-go"					
Excessive pleasurable involvements		 	 		
Distractibility/ attention problem					
Problems with peer relations					
Explosive, meltdowns, irritability		 	 		
Excitable, impulsive,					
Muscle tics/ vocal tics					
Aggressiveness					
Anxiety					
Depression/ sadness					
Talking too fast/ too much					
Decreased need for sleep					
Grandiosity, inflated self-esteem					
Hallucinations (auditory/ visual)					
POSSIBLE SIDE EFFECTS					
Increased appetite					
Nausea, constipation, diarrhea					
Irritability/ sadness/ social withdrawal					
Movements, twitches, tremors					
Head/ stomach/ muscle aches					
Drowsiness/ fatigue					
Stares off/ daydreams/ mental slowing					
Dry mouth					
Blurred/ double vision					
Rash, itchiness					

NEUROLEPTIC MED PROTOCOL

Some neuroleptics used in the treatment of mood regulation disorders and tics:

- Risperidone (Risperdal) 1 mg/ 1 ml, tabs 0.25, 0.5, 1,2,3,4 mg or solutabs (no 0.25)
- Apiprazole (Abilify) 1 mg/1ml, tabs: 2,5,10,15,20 mg
- Quetiapine (Seroquel) 25,50,100,200,300,400 mg tabs
- Ziprasidone (Geodon) 20, 40, 60, 80 mg tabs
- Olanzapine (Zyprexa) 2.5,5,7.5,10,15,20 mg tabs or solutabs 5.10,15,20

Before beginning any medication, parents should have a clear understanding of the diagnosis, purpose of treatment, types of available treatments, "off-label" use of medications which are not specifically approved by the FDA for use in pediatrics, known efficacy of available treatments, known side effects of available treatments, expected outcome with no treatment, expected efficacy of suggested treatment, expected side effects of suggested treatment, confidentiality, emergency procedures, monitoring and follow-up. If they do not feel that they have given informed consent, then they should not administer the medication.

DIRECTIONS FOR MEDICATION TRIAL:

- Adjustments: Side effects tend to happen early, usually within days of each dose change. Although <u>peak benefits</u> happen late, usually after a few months, you may see the <u>beginning</u> <u>of benefits</u> earlier, sometimes even within the first week. After one week at each dose, compare baseline ratings before medication with updated ratings:
 - a. "Looking good": If benefits are optimal (2s and 3s are down to 0s and 1s) and side effects are <u>in</u>significant (numbers on the bottom half of the page have not gone up), then stay with that dose.
 - b. "Too low": If benefits are less than optimal and side effects are <u>in</u>significant, then increase the dose by an amount equal to the starting dose.
 - c. "Hopefully just an adjustment": If benefits are optimal but there are significant side effects, call me. We will probably decrease the dose by 1/4-1/2 the starting dose. Call me again after this adjustment if side effects do not lessen each day.
 - d. "No good": If benefits are less than optimal and there are significant side effects, call me. Remembering that side effects can happen before benefits, we will either decrease the dose by ½ (and give the maximum <u>tolerated</u> dose a chance to work) or just stop and consider trying something else.