

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 04/05/2021

Completion of this form is voluntary. If informed consent is not given, the medication cannot be administered without a court order unless in an emergency.

This consent is maintained in the client's record and is accessible to authorized users.

Name – Patient / Client (Last, First MI)		ID Number	Living Unit	Date of Birth
Name – Individual Preparing This Form		Name – Staff Contact		Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Central Nervous System Stimulant	Focalin (dexamethylphenidate immediate release), Focalin XR (dexamethylphenidate delayed release)	Immediate release tablets: 5 mg – 20 mg daily Extended release tablets: 5 mg – 40 mg daily	

The anticipated dosage range is to be individualized, may be above or below the recommended range but no medication will be administered without your informed and written consent.

Recommended daily total dosage range of manufacturer, as stated in *Physician's Desk Reference* (PDR) or another standard reference.

This medication will be administered ☐ Orally ☐ Injection ☐ Other – Specify:

1. Reason for Use of Psychotropic Medication and Benefits Expected (note if this is 'Off-Label' Use)

Include DSM-5 diagnosis or the diagnostic impression ("working hypothesis.")

2. Alternative mode(s) of treatment other than OR in addition to medications include

Note: Some of these would be applicable only in an inpatient environment.

- ☐ Environment and/or staff changes
- ☐ Rehabilitation treatments/therapy (OT, PT, AT)
- ☐ Positive redirection and staff interaction
- ☐ Treatment programs and approaches (habilitation)
- ☐ Individual and/or group therapy
- ☐ Use of behavior intervention techniques

Other Alternatives:

3. Probable consequences of NOT receiving the proposed medication are

Impairment of ☐ Work Activities ☐ Family Relationships ☐ Social Functioning

Possible increase in symptoms leading to potential

- ☐ Use of seclusion or restraint
- ☐ Limits on recreation and leisure activities
- ☐ Limits on access to possessions
- ☐ Intervention of law enforcement authorities
- ☐ Limits on personal freedoms
- ☐ Risk of harm to self or others
- ☐ Limit participation in treatment and activities

Other Consequences:

**Note:** These consequences may vary depending upon whether or not the individual is in an inpatient setting. It is also possible that in unusual situations, little or no adverse consequences may occur if the medications are not administered.

See Page 2

Client Initial \_\_\_\_\_ Date \_\_\_\_\_

4. Possible side effects, warnings, and cautions associated with this medication are listed below. This is not an all-inclusive list but is representative of items of potential clinical significance to you. For more information on this medication, you may consult further with your physician or refer to a standard text, such as the PDR. As part of monitoring some of these potential side effects, your physician may order laboratory or other tests. The treatment team will closely monitor individuals who are unable to readily communicate side effects in order to enhance care and treatment.

Continued – Possible side effects, warnings, and cautions associated with this medication.

**Most Common Side Effects:** headache; insomnia (difficulty falling asleep or staying asleep); jitteriness; anxiety; dry mouth; abdominal pain; decreased appetite.

**Less Common Side Effects:** dizziness; depression; changes in emotion; itchy skin; nausea; heartburn; acidic taste in mouth or stomach acid regurgitation; vomiting; anorexia; chest or throat pain; nasal congestion; fever; weight loss; stunted growth in children; drug dependence; increased blood pressure.

**Rare Side Effects:** Although rare, please check with your doctor as soon as possible if any of the following side effects occur: blurred vision or changes in vision; anxiety; bigger, dilated, or enlarged pupils (black part of eye); loss of consciousness; chest pain or discomfort; severe mental confusion; severe dizziness; fainting; false or unusual sense of well-being; fast, slow, or irregular heartbeat; fever; hallucinations; severe headache; holding false beliefs that cannot be changed by fact; hyperventilation; increased sensitivity of eyes to light; irritability; lightheadedness; muscle twitching; nervousness; changes in hearing; redness of the face, neck, arms and occasionally, upper chest; restlessness; seizures; shortness of breath; excessive sweating; tremors such as shakiness; severe muscle pain; swelling of the face, tongue or lips; an erection lasting more than 4 hours.

### Caution

- **Withdrawal**

Do not abruptly stop taking this medication. If you have questions concerning this medication, please contact your doctor first and they will help you find an appropriate plan. After you stop using this medicine, your body may need time to adjust. The length of time this takes depends on the amount of medicine you were using and how long you used it. During this period of time check with your doctor if you notice any of the following side effects: mental depression; nausea or vomiting; stomach cramps or pain; trembling; unusual tiredness or weakness

- **Tourette's syndrome**

Stimulants, such as dexmethylphenidate, may make the muscle or verbal tics in Tourette's worse. If you or your child experiences and increase in tics while taking this medication, please call your doctor. Stimulants should generally be avoided in this population.

- **Raynaud's disease**

Although rare, episodes of ulcers or skin changes in the fingers or toes have been reported while taking this medication. If you notice ulceration or other skin changes on your fingers or toes after starting this medication, call your doctor right away.

- **Rhabdomyolysis**

Although rare, rhabdomyolysis is usually first identified by muscle pain or weakness. If you notice unusual muscle pain or weakness, and you cannot identify a cause, such as exercise, please call your doctor right away.

- **Serotonin syndrome**

Potentially life-threatening serotonin syndrome may occur when dexmethylphenidate is used in combination with other serotonergic agents (eg, selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, St. John's wort, tryptophan). Symptoms of serotonin syndrome include restless, overactive muscle reflexes, shivering, excessive sweating, tremors, agitation, fever, confusion, and pounding heartbeat.

- **Cardiovascular events**

CNS stimulant treatment has been associated with sudden death in children and adolescents with preexisting structural cardiac abnormalities and sudden death, stroke, and MI have been reported in adults.

- **Psychosis**

Use with caution in patients with preexisting psychosis (may exacerbate symptoms of behavior and thought disorder) or bipolar disorder (may induce mixed/manic episode). New-onset psychosis or mania may occur with stimulant use. Patients should be screened for bipolar disorder and risk factors for developing a manic episode prior to treatment (eg, comorbid or history of depressive symptoms; family history of suicide, bipolar disorder, or depression); consider discontinuation if psychotic or manic symptoms (eg, delusional thinking, hallucinations, mania) occur.

- **Insomnia management**

For patients taking the short-acting form of this medicine: Take the last dose for each day at least 6 hours before bedtime to help prevent trouble in sleeping. For patients taking the long-acting form of this medicine: Take the daily dose when you wake up to help prevent trouble in sleeping. These capsules or tablets should be swallowed whole. For the extended release (XR), or long-acting form, DO NOT break, crush, or chew them before swallowing.

**Warning: [Black Box Warning]: Abuse and dependence:** Amphetamines have a high potential for abuse. Particular attention should be paid to the possibility of subjects obtaining amphetamines for non-therapeutic use or distribution to others, and the drugs should be prescribed or dispensed sparingly.

Drug dependence--Administration of amphetamines for prolonged periods of time may lead to drug dependence and must be avoided.

Serious Adverse Events—Misuse of amphetamines may cause sudden death and serious cardiovascular adverse event

Chronic abusive use can lead to a marked tolerance and psychological dependence with varying degree of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Should be given cautiously to patients with a history of drug dependence or alcoholism. Careful supervision required during drug withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up. Should be given cautiously to emotionally unstable patients, such as those with a history of drug dependence or alcoholism, because such patients may increase dosage on their own initiative. Careful supervision required during drug withdrawal, since severe depression as well as the effects of chronic over activity can be unmasked. Long term follow-up may be required because of the patient's basic personality disturbances.

See standard reference text for an all-inclusive list of side effects.

**By my signature below, I GIVE consent for the named medication on Page 1 and anticipated dosage range. My signature also indicates that I understand the following:**

1. I can refuse to give consent or can withdraw my consent at any time with written notification to the institution director or designee. This will not affect my right to change my decision at a later date. If I withdraw consent after a medication is started, I realize that the medication may not be discontinued immediately. Rather, it will be tapered as rapidly as medically safe and then discontinued so as to prevent an adverse medical consequence, such as seizures, due to rapid medication withdrawal.
2. Questions regarding this medication can be discussed with the Interdisciplinary Team, including the physician. The staff contact person can assist in making any necessary arrangements.
3. Questions regarding any behavior support plan or behavior intervention plan, which correspond with the use of the medication, can be directed to the client's social worker, case manager, or psychologist.
4. I have the right to request a review at any time of my record, pursuant to § 51.30(4)(d) or § 51.30(5)(b).
5. I have a legal right to file a complaint if I feel that client rights have been inappropriately restricted. The client's social worker, case manager, or agency/facility client rights specialist may be contacted for assistance.
6. My consent permits the dose to be changed within the **anticipated dosage range** without signing another consent.
7. I understand the reasons for the use of the medication, its potential risks and benefits, other alternative treatment(s), and the probable consequences that may occur if the proposed medication is not given. I have been given adequate time to study the information and find the information to be specific, accurate, and complete.
8. This medication consent is for a period effective immediately and not to exceed fifteen (15) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by the Interdisciplinary Team. The goal, on behalf of the client, will be to arrive at and maintain the client at the minimum effective dose.

#### SIGNATURES

#### DATE SIGNED

Client – If Presumed Competent to Consent/Parent of Minor/Guardian (POA-HC)	Relationship to Client <input type="checkbox"/> Self <input type="checkbox"/> Parent <input type="checkbox"/> Guardian (POA-HC)	
Staff Present at Oral Discussion	Title	
Client / Parent of Minor / Guardian (POA-HC) Comments		

**As parent/guardian (POA-HC) was not available for signature, he/she was verbally informed of the information in this consent.**

#### Verbal Consent

Obtained by – PRINT – Staff Name	Date Obtained	Written Consent Received <input type="checkbox"/> Yes <input type="checkbox"/> No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received