

INFORMED CONSENT FOR MEDICATION

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
Antipsychotic – First Generation (Typical); Phenothiazine Derivative	Prolixin® (fluphenazine hydrochloride) Prolixin Decanoate® (fluphenazine decanoate )	Oral: 2.5 mg to 40 mg per day Short-acting Injection: 1.25 mg to 10mg per day Decanoate Injection: 3.125 mg to 100 mg every one to three weeks	

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
- ☐ Positive redirection and staff interaction
- ☐ Individual and/or group therapy
- ☐ Rehabilitation treatments/therapy (OT, PT, AT)
- ☐ Treatment programs and approaches (habilitation)
- ☐ 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 access to possessions
- ☐ Limits on personal freedoms
- ☐ Limit participation in treatment and activities
- ☐ Limits on recreation and leisure activities
- ☐ Intervention of law enforcement authorities
- ☐ Risk of harm to self or others

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

**Other Consequences:**


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**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.

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

**Most Common Side Effects** hypotension (low blood pressure), extrapyramidal disease, tardive dyskinesia

**Less Common Side Effects** prolonged QT interval, paralytic ileus, agranulocytosis, leukopenia, neutropenia, thrombocytopenia, liver damage, systemic lupus erythematosus

**Rare Side Effects** neuroleptic malignant syndrome (symptoms: severe confusion or coma; difficult or fast breathing; drooling; fast heartbeat; high/low irregular blood pressure; increased sweating; loss of bladder control; severe muscle stiffness; trembling or shaking; trouble with speaking or swallowing)

**Caution****Precautions:**

**Access:** While coadministration of medication-assisted treatment drugs (MAT, eg, methadone and buprenorphine) and benzodiazepines or other CNS depressants (including alcohol) may increase the possibility of harm, including overdose and death, concomitant therapy with MAT may be appropriate in some patients; if concomitant use is necessary, careful management and monitoring recommended.

**Cardiovascular:** Use caution in patients with cardiovascular disease, including mitral insufficiency.

**Concomitant use:** Coadministration of central nervous system depressants, including antipsychotics, with opioids may result in profound sedation, respiratory depression, coma, or death. The addition of a sedating antipsychotic, including fluphenazine, to prescription opioids was associated with significantly higher risk of unintentional overdose within 30 days compared with nonsedating antipsychotics; consider a nonsedating antipsychotic whenever coadministration with opioids is required.

**Endocrine and metabolic:** Use caution in patients with pheochromocytoma.

**Environmental exposure:** Use caution in patients exposed to extreme heat or phosphorus insecticides.

**Hematologic:** Agranulocytosis, leukopenia, and neutropenia may occur, with increased risk in patients with preexisting low WBC or history of drug-induced leukopenia or neutropenia; monitoring recommended and discontinuation of therapy may be necessary.

**Hepatic:** Liver damage may occur with prolonged therapy; monitoring recommended.

**Immunologic:** Cross-sensitivity may occur in patients with previous phenothiazine hypersensitivity reactions including cholestatic jaundice, dermatoses, or other allergic reactions.

**Neurologic:** Potentially irreversible tardive dyskinesia may occur; risk increased in elderly patients, especially elderly women, and with increased duration of treatment and total cumulative dose; consider discontinuation of treatment. Potentially fatal neuroleptic malignant syndrome has been reported in association with antipsychotic drugs; discontinue immediately if suspected. The mental and physical abilities required for driving a car or operating heavy machinery may be impaired. Use caution in patients with seizure disorder; grand mal convulsions have occurred.

**Ophthalmic:** Pigmentary retinopathy, corneal deposits, and lenticular deposits may occur with prolonged therapy.

**Respiratory:** Silent pneumonia may occur.

**Special populations (Beers Criteria):** Avoid use due to an increased risk of cerebrovascular accident. Exceptions are used for schizophrenia, bipolar disorder, adjunctive treatment of major depressive disorder, or short-term use as antiemetic during chemotherapy. Avoid use for behavioral problems of dementia or delirium in elderly as antipsychotics may increase the rate of cognitive decline and mortality (unless nonpharmacological measures fail, and the patient is a threat to self or others). If use is required, consider periodic discontinuation to assess need and/or lowest effective dose. Avoid use in elderly patients with Parkinson's Disease as symptoms may worsen and in patients with a history of falls or fractures (unless safer alternatives are not available) due to risk for ataxia, impaired psychomotor performance, syncope or additional falls. If used, caution is advised, and monitoring is recommended as SIADH or hyponatremia may occur or be exacerbated. Avoid concomitant use of 3 or more CNS-active agents in any combination due to increased risk of falls.

Special populations (KIDs List): Avoid in infants and use caution in children due to risk of acute dystonia (dyskinesia); increased risk of respiratory depression, extravasation, and death with IV use.

Surgery: Hypotensive phenomena may occur in psychotic patients receiving large phenothiazine doses; monitoring recommended and reduced amounts of anesthetics or CNS depressants may be warranted.

### Warning

Black Box Warning:

Fluphenazine Hydrochloride: Injection (solution), Oral (elixir; tablet)

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. Fluphenazine hydrochloride is not approved for the treatment of patients with dementia-related psychosis.

**Syndrome Note** Neuroleptic malignant syndrome: Neuroleptic Malignant Syndrome (NMS) has been reported with antipsychotic drugs and may be fatal. May manifest as hyperpyrexia, muscle rigidity, altered mental status, evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmias). Symptoms persisted for 12 to 13 days after stopping the neuroleptic. Diagnosis is complicated; differential diagnosis should account for the possibility of both serious illness and untreated extrapyramidal signs, as well as central anticholinergic toxicity, heat stroke, drug fever, and primary CNS pathology.

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