

### 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
Antianxiety agent (benzodiazepine)	Tranxene® (clorazepate)	3.75 mg - 60 mg	

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.

- |   |   |
|---|---|
| <input type="checkbox"/> Environment and/or staff changes           | <input type="checkbox"/> Rehabilitation treatments/therapy (OT, PT, AT)   |
| <input type="checkbox"/> Positive redirection and staff interaction | <input type="checkbox"/> Treatment programs and approaches (habilitation) |
| <input type="checkbox"/> Individual and/or group therapy            | <input type="checkbox"/> 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

- |  |  |
|--|--|
| <input type="checkbox"/> Use of seclusion or restraint                   | <input type="checkbox"/> Limits on recreation and leisure activities |
| <input type="checkbox"/> Limits on access to possessions                 | <input type="checkbox"/> Intervention of law enforcement authorities |
| <input type="checkbox"/> Limits on personal freedoms                     | <input type="checkbox"/> Risk of harm to self or others              |
| <input type="checkbox"/> 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.

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** drowsiness, dizziness.

**Less Common Side Effects** gastrointestinal complaints, nervousness, blurred vision, dry mouth, headache, and mental confusion

#### Rare Side Effects

#### Caution

Precautions:

Access: FDA is advising that the opioid addiction medications buprenorphine or methadone should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS). The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction can outweigh these risks. Careful medication management by health care professionals can reduce these risks.

Concomitant use: Avoid use with other CNS depressants.

Hepatic: Use caution in patients with impaired hepatic function.

Neurologic: Interference with psychomotor performance may occur; use caution when engaging in hazardous occupations requiring mental alertness (eg, operating dangerous machinery including motor vehicles). Ataxia or excessive sedation may occur in elderly or debilitated patients; dosage adjustments and monitoring recommended.

Psychiatric: Use not recommended in depressive neuroses or psychotic reactions. Increased risk of suicidal thoughts or behavior has been reported; monitoring recommended. Use with caution for treatment of anxiety when there is any evidence of impending depression as suicidal tendencies may occur; protective measures may be necessary.

Renal: Use caution in patients with impaired renal function.

Reproductive: Use during the later stages of pregnancy can result in neonatal sedation (eg, respiratory depression, lethargy, hypotonia) and neonatal withdrawal syndrome (eg, hyperreflexia, irritability, restlessness, tremors, inconsolable crying, and feeding difficulties); monitoring required and medical management may be necessary.

Special populations (Beers Criteria): Avoid use in elderly due to greater benzodiazepine sensitivity, especially in patients with a history of falls or fractures (unless safer alternatives are not available), cognitive impairment or dementia, or with delirium or at high risk for delirium. May increase risk of syncope, falls fractures, ataxia, cognitive or psychomotor impairment, motor vehicle accidents, delirium, or other adverse CNS effects (may be appropriate for seizure disorders, rapid eye movement sleep disorders, benzodiazepine or ethanol withdrawal, severe generalized anxiety disorder, periprocedural anesthesia, and end-of-life care). Avoid concomitant use of 3 or more CNS-active agents in any combination due to increased risk of falls and fractures. Avoid concomitant use of any opioid due to increased risk of overdose.

Pediatrics: Use not recommended in pediatric patients younger than 9 years of age.

Withdrawal: A protracted withdrawal syndrome with symptoms lasting weeks to more than 12 months has been reported in patients taking benzodiazepines.

#### Warning

Black Box Warning: Oral (Tablet)

Risks from Concomitant Use with Opioids; Abuse, Misuse, and Addiction; and Dependence and Withdrawal Reactions

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation. The use of benzodiazepines, including clorazepate, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes. Before prescribing clorazepate and throughout treatment, assess each patient's risk for abuse, misuse, and addiction. The continued use of benzodiazepines, including clorazepate, may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. Abrupt discontinuation or rapid dosage reduction of clorazepate after continued use may precipitate acute withdrawal reactions, which can be life-threatening. To reduce the risk of withdrawal reactions, use a gradual taper to discontinue clorazepate or reduce the dosage.

**Syndrome Note**

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