California Association of Health Facilities
2201 K Street. Sacramento, California 95816

Informed Consent Tool Kit for-RESIDENTS WITH BEHAVIOR AND PSYCHOTIC SYMPTOMS OF DEMENTIA

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EXHIBITS

DISCLAIMER

This INFORMED CONSENT TOOL KIT FOR RESIDENTS WITH BEHAVIOR AND PSYCHOTIC SYMPTOMS OF DEMENTIA document from the California Association of Health Facilities (CAHF) is exclusively intended to provide guidance. It does not contain or constitute legal advice in any form and does not make any assurance or representation that the guidance contained herein will be determined to constitute compliance with any state or federal law or regulation. In addition, CAHF is not responsible for any errors or omissions contained in the INFORMED CONSENT TOOL KIT FOR RESIDENTS WITH BEHAVIOR AND PSYCHOTIC SYMPTOMS OF DEMENTIA and assumes no responsibility for the misuse or erroneous interpretation of its contents.

Informed Consent Tool Kit

INFORMED CONSENT VERIFICATION FOR ANTIPSYCHOTIC/PSYCHOTHERAPEUTIC MEDICATIONS Reference: Title 22, CCR, Section 72527 and 72528, Health and Safety Code (HSC Sections 1418.8 and 1418.9)
The facility shall verify that the physician has obtained informed consent as follows:
• Prior to initiation of antipsychotic or other psychotherapeutic medication;
• Prior to increase in dosage of an antipsychotic medication.
A.PHYSICIAN/ HEALTHCARE PRACTITIONER RESPONSIBILITY Reference: HSC 1418.9, Title 22, CCR, Section 72528, CFR §483.75(i) F Tag 501 **The physician is the sole healthcare practitioner who is authorized to obtain informed consent for antipsychotic medications**. **Informed consent must include material information as specified in state regulation.** NOTE: Other healthcare practitioners, within the scope of their licensure, may obtain informed consent for all other types of psychotherapeutic medications.
The physician will discuss with the resident/ responsible party (RP) information that is material to obtaining informed consent. (See CAHF Exhibits 1A and 1B for examples of the type of written information that the physician may provide.)
Within 48 hours of initiating or increasing the dose of an antipsychotic medication, when the resident consents to notify an interested family member the physician or designee shall make reasonable attempts to make such notification.
B. FACILITY ROLE IN INFORMED CONSENT Reference: HSC 1418.9, Title 22, CCR, Section 72528, CFR §483.75(i) F Tag 501
As specified in state regulation and statute, the facility's role in the informed consent process is limited to verifying that the physician obtained informed consent. The physician and/or licensed healthcare practitioner (as appropriate) within the scope of his/her licensure is deemed to have the technical knowledge to assure adequate disclosure of information, including that pertaining to the risks of treatment, has been given to the resident or RP.
• The facility has written patients' rights policies and procedures related to antipsychotic/psychotherapeutic medication informed consent that include: • How the facility will verify that informed consent was obtained or refused that identifies all ways in which verification may occur and be documented in the resident record. • How the facility, in consultation with the resident's physician will identify who may serve as a resident's representative when an incapacitated patient has no conservator or attorney in fact under a valid Durable Power of Attorney for Health Care. • The medical director has ensured that resident care policies and procedures were implemented.
• Implemented regarding antipsychotic informed consent.
C. DOCUMENTING VERIFICATION OF INFORMED CONSENT Reference: Title 22, CCR, Section 72527 and 72528, CFR §483.75(i) F Tag 501
The resident record must reflect that informed consent has been obtained by the healthcare practitioner **NOTE**: Only a physician may obtain informed consent for antipsychotic medication from the resident/RP. Documentation may include one or more of the following:
• A copy of the informed consent obtained by the healthcare practitioner ordering the medication prior to admission to facility.
• The healthcare practitioner's signature and/or notes in the resident record verifying that

informed consent has been obtained from the resident/RP.
• The signature of the licensed nurse verifying receipt of a verbal and/or written confirmation from the healthcare practitioner that informed consent has been obtained.
• A signed copy of "Verification of Informed Consent for Antipsychotic Medication (see CAHF sample form 1-1)
OR
• For psychotherapeutic medication: a signed copy of "Verification of Informed Consent for Psychotherapeutic Medication (see CAHF sample form 1-2).
• A signed copy of "Resident/RP Consent for Use of Antipsychotic Medication (see CAHF sample form 2-1)
OR
• A signed copy of "Resident/RP Consent for Use of Psychotherapeutic Medication (see CAHF sample form 2-2)
D. FACILITY OBLIGATION TO FULLY INFORM RESIDENT/RP OF HEALTH STATUS Reference: CFR § 483.10(b)(2) and (3) F Tags 153 and 154
The facility is responsible for assuring: • Each resident is fully informed of his or her total health status, including but not limited to his/her medical condition. • The resident is fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being. • At any time, should the resident/RP indicate doubt or confusion about the use of antipsychotic/psychotherapeutic medication, or withdraw consent for same, contact the physician and/or the licensed health care practitioner (as appropriate).
E. EXCEPTIONS TO OBTAINING INFORMED CONSENT Reference: Title 22, CCR, Section 72528
There is documentation within the resident record that any of the following conditions are present:
• An emergency exists where there is an unanticipated condition in which immediate action is necessary for the preservation of life or the prevention of serious bodily hat, to the resident or others or to alleviate severe physical pain, and it is impractical to obtain the required consent and that the action taken is within the customary practice of the licensed healthcare practitioners of good standing acting within the scope of their professional licensure in similar circumstances.
• The resident or RP specifically requested that he/she is not to be informed of the risks of the recommended treatment

- That the licensed healthcare practitioner acting within his/her scope of professional licensure, relied upon objective facts, as documented in the health record, that would demonstrate to a reasonable person that the disclosure would have so seriously upset the resident that the resident would not have been able to rationally weight the risks of refusing to undergo the recommended treatment and that, unless inappropriate, a resident's representative gave informed consent as set forth herein.

F. RESIDENT LACKS CAPACITY AND NO LEGALLY AUTHORIZED DECISION MAKER

Reference: HSC Section, 1418.8

Requirement:

If the attending physician determines the resident lacks capacity and there is no person with legal authority to make those decisions on behalf of the resident, the MD shall inform the facility.

- The resident record contains documentation that there is no person who has legal authority who can or will make health care decisions as determined by the attending physician.

- IDT will review the proposed prescribed medical intervention prior to the administration of the proposed medication.

- The IDT shall include a registered nurse who has responsibility for the resident, other appropriate staff in disciplines as determined by the resident's needs and, where practicable, a patient representative.

The IDT review shall include the following:

- A review of the physician's assessment of the resident's condition.
- The reason for the proposed use of the medical intervention.
- The type of medical intervention to be used in the resident's care including its probable frequency and duration.
- The probable impact on the resident's condition, with and without the use of the medical intervention.
- Reasonable alternative medical interventions considered or utilized and reasons for their discontinuance or inappropriateness.

The IDT shall periodically evaluate the use of the prescribed medical intervention at least quarterly or upon a significant change in the resident's medical condition.

- **EXCEPTION**: In the case of an emergency, a medical intervention may be administered which requires informed consent prior to convening an IDT review. The IDT shall meet within one week of the emergency for evaluation of the medical intervention.

Verification of Informed Consent for Antipsychotic Medication

Resident name: _____

Medication : _____ *Expected Dosage Range:* _____

Specific medical condition / psychiatric diagnosis:

- ☐ Schizophrenia
- ☐ Schizoaffective Disorder
- ☐ Delusional Disorder
- ☐ Mood Disorders (e.g., Bipolar Disorder, Depression with Psychotic Features, Refractory Depression)
- ☐ Schizophreniform Disorders
- ☐ Psychosis
- ☐ Brief Psychotic Disorder
- ☐ Dementing illnesses w/ associated behavioral symptoms
- ☐ Medical illnesses w/psychotic symptoms and/or related to psychosis/ mania/delirium
- ☐ Tourette's or Huntington's
- ☐ Hiccups or Nausea and Vomiting associated with cancer or chemotherapy
- ☐ Other: _____

Potential/Expected Benefits:

Side Effects / Severity of Risks:

☐ Physician requests the facility send attached information about the medication and a copy of this form to resident and/or resident's surrogate decision-maker. Date sent _____ Signature _____

Warning for Antipsychotic Medication

The Food and Drug Administration (FDA) issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that the death rates are higher for elderly people with dementia when taking this medication. A review of the data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA approved for the treatment of behavioral disorders in patients with dementia. Source: National Institute of Mental Health U.S. Department of Health and Human Services www.nih.gov

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

I have discussed with _____, the following:
Circle one: resident and/or the resident's surrogate decision-maker

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ The above-named resident and/or the resident's surrogate decision-maker has given permission for use of the medication.

☐ The above-named resident has given permission to contact a designated family member regarding the use of anti-psychotic medication.

☐ The above-named resident has <u>not given permission</u> to contact a designated family member regarding the use of anti-psychotic medication.

_____
Ordering Physician's Signature Date

_____
Licensed Nurse Signature Verifying Evidence of Informed Consent Date

CAHF – Form 1 - 1
Nov. 6, 2012

Resident/Surrogate Decision Maker Informed Consent for Antipsychotic Medication

Resident name: _____

Medication : _____ *Expected Dosage Range:* _____

Specific medical condition / psychiatric diagnosis:

- ☐ Schizophrenia
- ☐ Schizoaffective Disorder
- ☐ Delusional Disorder
- ☐ Mood Disorders (e.g., Bipolar Disorder, Depression with Psychotic Features, Refractory Depression)
- ☐ Schizophreniform Disorders
- ☐ Psychosis
- ☐ Brief Psychotic Disorder
- ☐ Dementing illnesses w/ associated behavioral symptoms
- ☐ Medical illnesses w/psychotic symptoms and/or related to psychosis/ mania/delirium
- ☐ Tourette's or Huntington's
- ☐ Hiccups or Nausea and Vomiting associated with cancer or chemotherapy
- ☐ Other: _____

Potential/Expected Benefits:

Side Effects / Severity of Risks:

☐ See attached information sheet for additional information about this medication

Warning for Antipsychotic Medication

The Food and Drug Administration (FDA) issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that the death rates are higher for elderly people with dementia when taking this medication. A review of the data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA approved for the treatment of behavioral disorders in patients with dementia. Source: National Institute of Mental Health U.S. Department of Health and Human Services www.nih.gov

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

The physician has discussed the following:

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ I have given permission for use of the medication.

_____

Resident Signature Date

or

_____

Resident's Surrogate Decision-maker Date

Verification of Informed Consent for Psychoactive Medication

Resident name: _____

Medication : _____	*Expected Dosage Range:* _____
Symptoms to be treated:	
Potential/Expected Benefits:	
Side Effects / Severity of Risks:	
☐ Physician requests the facility send attached information about the medication and a copy of this form to resident and/or resident's surrogate decision-maker. Date sent _____ Signature _____	

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

I have discussed with _____, the following:
Circle one: resident and/or the resident's surrogate decision-maker

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ The above-named resident and/or the resident's surrogate decision-maker has given permission for use of the medication.

_____
Ordering Physician's Signature Date

_____
Licensed Nurse Signature Verifying Evidence of Informed Consent Date

Resident/Surrogate Decision Maker Informed Consent for Psychoactive Medication

Resident name: _____

Medication : _____	*Expected Dosage Range:* _____
Symptoms to be treated:	
Potential/Expected Benefits:	
Side Effects / Severity of Risks:	
☐ See attached information sheet for additional information about this medication	

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

The physician has discussed the following:

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ I have given permission for use of the medication.

_____

Resident Signature Date

or

_____

Resident's Surrogate Decision-maker Date

Patient Information Sheet

Clozapine
(marketed as Clozaril)

This is a summary of the most important information about Clozaril. For details, talk to your healthcare professional.

What is Clozaril?

Clozaril is a prescription medicine used to treat people with severe forms of schizophrenia that have not responded to or cannot take other treatments. Clozaril is also used to lower the risk of suicidal behavior in people with schizophrenia or schizoaffective disorder. Clozaril is not approved for use in children.

Who Should Not Take Clozaril?

You should not take Clozaril if:

- You are taking other medicines that can cause the same serious bone marrow side effects as Clozaril.
- You can ask your healthcare professional for a complete list of these medications.

What are The Risks?

The following are the risks and potential side effects of Clozaril therapy. However, this list is not complete.

- ***Increased chance of death in elderly persons.*** Elderly patients treated with atypical antipsychotics, such as Clozaril, for dementia had a higher chance for death than patients who did not take the medicine. Clozaril is not approved for dementia.
- ***Agranulocytosis,*** a potentially life-threatening reaction where the body's bone marrow does not produce enough white blood cells. Because of this risk, your healthcare professional must monitor your blood while you are taking Clozaril.
- ***Seizures***. The risk of seizure is increased in people who have a history of seizures or other predisposing factors. Because of this risk you should not engage in any activity where you may suddenly lose consciousness, such as operating complex machinery, driving, swimming, climbing, etc.
- ***Heart problems***. Clozaril can cause a condition called myocarditis, or swelling of the heart muscle. Some of the warning signs of myocarditis are tiredness, shortness of breath, rapid breathing, fever, chest pain, and irregular heart beat. If these happen, call your healthcare professional right away.
- ***Lowering of blood pressure*** when you stand up. This may also lead to fainting. In rare instances, this has been associated with lung and/or heart collapse.

Clozaril and other antipsychotic medications can cause serious problems such as:

- ***A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS).*** NMS can cause a high fever, stiff muscles, sweating, a fast or irregular heart beat, change in blood pressure, and confusion. NMS can affect your kidneys. NMS is a medical emergency. Call your healthcare professional right away if you experience these symptoms.
- ***A movement problem called tardive dyskinesia (TD).*** Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- ***High blood sugar and diabetes.*** Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.
- ***Other serious side effects may*** include fever, blood clots in the lung, increased blood sugar, and liver disease.
- ***The most common side effects*** include drowsiness, increased salivation, rapid heart beat, dizziness, constipation, headache, shaking, and lightheadedness.

What Should I Tell My Healthcare Professional?

Before you start using Clozaril, tell your healthcare professional if you:

- have or had heart or lung problems
- have or had seizures
- have or had blood clots
- have or had diabetes or increased blood sugar
- have or had liver disease
- have or had glaucoma
- have or had stomach problems
- have or had prostate enlargement
- are trying to become pregnant, are already pregnant, or are breast-feeding
- drink alcohol
- smoke

Clozapine
(marketed as Clozaril)

Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with Clozaril, review all medications that you are taking with your health care professional, including those that you take without a prescription. You should not take Clozaril if you are taking other medicines that can cause the same serious bone marrow side effects as Clozaril.

Your healthcare professional may have to adjust your dose or watch you more closely if you take the following medications:

- certain medicines used to treat anxiety, called benzodiazepines
- certain medicines used to clear thoughts, called psychotropic drugs
- epinephrine
- phenytoin
- rifampin
- cimetidine
- erythromycin
- carbamazepine
- fluvoxamine
- paroxetine

Avoid drinking alcohol while taking Clozaril.

Is There Anything Else I Need to Know?

- Dizziness, and sometimes fainting, caused by a drop in blood pressure may happen with Clozaril, especially when you first start taking this medicine or when the dose is increased.

- Clozaril may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how Clozaril affects you.

Clozaril FDA Approved 1989
Patient Information Sheet Revised 09/2006

Mental Health Medications: Antipsychotics

Adapted from Mental Health Medications – National Institute of Mental Health
U.S. Department of Health and Human Services

To see more go to:

www.nih.gov

-Click on "Health Topics"
-Click on "Publications"
-Select "Mental Health Medications"

You Have The Right To be Fully Informed About The Benefits and Risks of Antipsychotic Medication

California Informed Consent Requirements

California Code of Regulations, Title 22 § 72528 (a) It is the responsibility of the attending licensed healthcare practitioner acting within the scope of his or her professional licensure to determine what information a reasonable person in the patient's condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. Information that is commonly appreciated need not be disclosed. The disclosure of the material information and obtaining informed consent shall be the responsibility of the physician. The disclosure of the material information and obtaining informed consent shall be the responsibility of the licensed healthcare practitioner who, acting within the scope of his or her professional licensure, performs or orders the procedure or treatment for which informed consent is required.

(b) The information material to a decision concerning the administration of a psychotherapeutic drug or physical restraint, or the prolonged use of a device that may lead to the inability of the patient to regain use of a normal bodily function shall include at least the following:

(1) The reason for the treatment and the nature and seriousness of the patient's illness.

(2) The nature of the procedures to be used in the proposed treatment including their probable frequency and duration.

(3) The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment.

(4) The nature, degree, duration and probability of the side effects and significant risks, commonly known by the health professions.

(5) The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment.

(6) That the patient has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

Your Company Logo will Appear Here

Mental Health Medications: Antipsychotics Benefits and Risks

Company Phone number
Company FAX number
Website Address
Company Address

Exhibit B

Mental Health Medications: Antipsychotics

Antipsychotic medications are used to treat schizophrenia and schizophrenia-related disorders, psychotic symptoms, hallucinations and delusions (breaks in reality). Some of the "typical" antipsychotics include:

- Chlorpromazine (Thorazine)
- Haloperidol (Haldol)
- Perphenazine
- Fluphenazine

In 2009 new antipsychotic medications were developed. These new medications are called second generation or "atypical" antipsychotics. Some of the "atypical" antipsychotics include:

- Risperidone (Risperdal)
- Olanzapine (Zyprexa)
- QueΘapine (Seroquel)
- Ziprasidone (Geodon)
- Aripiprazole (Abilify)
- Paliperidone (Invega)

NOTE: The FDA issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that the death rates are higher for elderly people with dementia when taking this medication. A review of the data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA approved for the treatment of behavioral disorders in patients with dementia.

What are the Side Effects?
Side effects may include, but not be limited to:

- Drowsiness
- Dizziness when changing posiΘons
- Blurred vision
- Rapid heartbeat
- SensiΘvity to the sun
- Skin rashes
- Major weight gain
- Changes in metabolism
- Rigidity
- Persistent muscle spasms
- Tremors restlessness

Long term use of typical antipsychotic medications may lead to a condition called tardive dyskinesia (TD). TD causes muscle movements a person cannot control the movements commonly happen around the mouth. TD can range from mild to severe, and in some people the problem cannot be cured. Sometimes people with TD recover partially or fully after they stop taking the medication.
Every year, an estimated 5 percent of people taking typical antipsychotics get TD. The condition happens to fewer people who take the new, atypical antipsychotics, but some people may still get TD.

How are Antipsychotics Taken and How do People Respond to Them?

Antipsychotics are usually pills that people swallow or liquid they can drink. Some antipsychotics are shots that are given once or twice a month.

Symptoms of schizophrenia, such as feeling agitated and having hallucinations, usually go away within days. Symptoms like delusions usually go away within a few weeks. After about six weeks, many people will see a lot of improvement.

Add Facility Information Here