



A Guide to Using the Informed Consent Verification Form

I. Informed Consent Generally.

Informed consent is a century-old American legal concept of personal autonomy. It entails the right of adults to control what happens to their bodies as well as the right to relevant information upon which to base health care decisions. Informed consent is also a process - not an event or a form - where adults are told about proposed health care treatment and given the opportunity to ask questions, seek clarification, and make the ultimate decision over whether to accept or reject the proposed treatment.

California laws and regulations* require skilled nursing facilities to verify residents' informed consent before administering psychotherapeutic drugs to residents. The detailed requirements of verifying consent are explained in the Department of Public Health's All-Facilities Letters [11-08](#) and [13-38](#).

Verifying informed consent requires facilities to ensure that either: 1) the resident for whom a psychotropic drug has been prescribed or 2) the resident's representative has agreed to administration of the drug after being told the relevant diagnosis, proposed benefits, potential risks, and alternatives to taking the drug. *The drug prescriber, not the skilled nursing facility staff*, is responsible for providing the information about diagnosis, risks, benefits, and alternatives. Nursing home staff are not permitted to obtain informed consent for psychotropic medications, although they can assist the prescriber by providing supportive information. The nursing home's role is to **verify** that informed consent was obtained. The verification must take place before the first administration of the medication.

II. Written Verification.

Informed consent can be verified in many possible ways, such as verbally or in writing. State law does not require any particular verification process. However, a best practice is to verify informed consent in writing. Written verification is good idea for several reasons:

- 1) *Promotes a Better Informed Consent Process.* This form includes important information regarding antipsychotic medications that many residents or their representatives would want to know. In addition, it requires signatures from the resident or their representative, the prescriber, and the nursing home staff which means all three of these important parties have a common understanding about the medication.
- 2) *Documentation.* Having the person who gave consent sign that they have given informed consent is strong proof that informed consent was obtained and the facility has complied with the legal standards.
- 3) *Can Prompt Further Discussion.* Presenting the form to a resident or their representative may prompt them to continue discussion with the prescriber about the proposed antipsychotic. If the resident or representative had not been fully engaged in their initial discussion with the prescriber, the form may encourage them to continue the discussion until all questions have been answered.

While written verification of informed consent is important, the form itself does not substitute for the conversation between the prescriber and the resident or the resident's representative! The form is meant to complete the informed consent process that must be undertaken by the resident's prescriber.

III. The Form.

Use of the form is completely voluntary for nursing homes - facilities are free to use their own form, revise this form as needed for their own use, or to not use a form at all.

It is strongly recommended that this form be printed, two-sided, on bright Martian Green paper so it is easily identifiable in the resident records. Currently, there are no non-English translations available.

The form has many important features. It only covers the use of antipsychotic medications. Other medications, including other psychotropic drugs, are not covered. The form is meant to give a very brief summary of some of the important features of antipsychotic medications and explain they should only be used after carefully considering other forms of treatment, particularly for a resident with dementia.

Page one of the form begins with important considerations about using antipsychotics as a treatment for dementia. In 2012, the Centers for Medicare & Medicaid Services initiated a national campaign to improve dementia care and reduce unnecessary antipsychotic use in nursing homes. (For more information, go to <https://www.nhqualitycampaign.org/dementiaCare.aspx>) California convened a unique partnership of nursing home providers, physicians, resident advocates, government agencies, and others to embrace the national initiative. Page one also includes some basic information about the medication (name, dose) and the condition for which it is prescribed. This should be completed by the prescriber or a nurse operating under the direction of the prescriber. The bottom of page one provides space for listing the risks, benefits, and possible alternatives. These spaces should not be left blank. Risks, benefits, and alternatives must be conveyed by the prescriber with the resident or their representative.

Page two of the form is for the prescriber to complete. The prescriber must explain the nature of the informed consent obtained and must sign the form. The resident or their representative must also sign. If for some exceptional reason, the resident's or a representative's signature cannot be obtained, a nurse from your facility's staff can sign that diligent efforts to obtain a signature were attempted but failed after informed consent was verified. If the resident's or a representative's signature cannot be obtained, informed consent must still be verified verbally.

Once all of the signatures have been obtained, give a copy of the form to the resident or their representative. It's recommended that written information about the proposed medication for the resident or their representative be attached. Since most residents never see the pharmacy packaging for their medication, additional information is important. There is a checkbox to indicate that additional information was provided. Two websites for medication information are listed at the bottom of page two.

For more information about improving dementia care or the California Partnership to Improve Dementia Care, please go to dementiacarerresourceCA.org

* Among the applicable state laws regarding informed consent for nursing home residents, see Health and Safety Code Section 1418.9 and 22 California Code of Regulations Section 72528.