



# Minnesota Informed Consent

*Overview and Form*

October 2007

On behalf of the Minnesota Alliance for Patient Safety (MAPS), we are pleased to introduce the model informed consent documents. MAPS has developed a template for an informed consent form and a model policy that meets documentation regulations and that patients can understand. The enclosed template for an informed consent form and the model policy are intended to serve as Minnesota's universal documentation of informed consent for health-care organizations throughout the state.

The form meets the minimum standards of informed consent as defined by the Centers for Medicare and Medicaid Services (CMS), including CMS final interpretive guidelines released April 2007, as well as standards of the Joint Commission, and the Occupational Safety and Health Administration (OSHA). The new CMS guidelines require that a written informed consent process and form be in the patient's chart prior to the surgery/invasive procedure.

The new CMS guidelines also require that, through the informed consent process, providers inform the patient of his or her health status and allow patients to be part of care planning. Health literacy is a real issue, regardless of education, economic status, or culture as patients are often faced with complex medical information and treatment decisions. The MAPS template for informed consent is written at a fourth grade reading level. A lower literacy level form does not preclude an in-depth conversation with those patients with higher levels of understanding.

We encourage organizations across the state to incorporate the MAPS template into their informed consent process and accept the MAPS informed consent documentation, identified by the MAPS logo, as a state standard for informed consent. The form and policy are posted on the MAPS web site, [www.mnpatientsafety.org](http://www.mnpatientsafety.org). If you have any questions, please contact Becky Schierman at [rschierman@mnmed.org](mailto:rschierman@mnmed.org), (612) 362-3766 or Tania Daniels at [tdaniels@mnhospitals.org](mailto:tdaniels@mnhospitals.org), (651) 641-1121.

Sincerely,

Robert K. Meiches, M.D., CEO  
Minnesota Medical Association

Bruce J. Rueben, President  
Minnesota Hospital Association



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Overview

The Minnesota Alliance for Patient Safety (MAPS) developed a statewide informed consent form and policy. MAPS envisions this form as Minnesota's universal documentation of informed consent and that health-care organizations statewide will use the informed consent form and accompanying policy with no variation. If this form is used, the MAPS logo should be included along with an organizational logo.

## THE FORM

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The form meets the requirements of the Centers for Medicare and Medicaid Services (CMS), the Joint Commission and the Occupational Safety and Health Administration (OSHA). It incorporates requirements identified in April 2007 CMS interpretative guidelines.

To make the form understandable to the majority of patients, the form was written at a fourth grade reading level. A lower reading level does not preclude an in-depth conversation with those patients with higher levels of understanding.

## THE POLICY

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The model policy contains the following information

1. definition of informed consent
2. purpose of the informed consent process
3. information that must be provided to the patient during the informed consent conversation
4. purpose of the informed consent form
5. information that must be included on the informed consent form (including minimum elements)
6. documentation of consent
7. physician's responsibility
8. facility's responsibility
9. scope of informed consent
10. procedures that may require more than one consent form
11. situations that require written informed consent
12. exceptions to informed consent requirement
13. timeliness of informed consent
14. individuals allowed to give informed consent

**To download the form or the policy, visit [www.mnpatientsafety.org](http://www.mnpatientsafety.org).**