Consent

Effective Date: August 06, 2010
No: HC-CLN-IHR-P003

POLICY:

This policy outlines when and how to properly obtain informed consent and who the appropriate individual is to provide informed consent.

Patients on research protocols are outside of the oversight of this policy. For current guidance, see http://www.ohsu.edu/xd/about/services/integrity/policies/irb-policies-by-category.cfm Research Consent forms must be filed in the patient's medical record.

PROCEDURE:

DEFINITIONS

Decision Making Capacity: The capacity to make health care decisions is a legal and ethical concept with the following four related elements:

a. Ability to understand basic information relevant to the treatment.
b. Ability to understand and appreciate consequences of the treatment.
c. Ability to process information rationally.
d. Ability to communicate choice.

For how to determine Decision Making Capacity, please refer to the Determining Capacity Policy (link coming soon).

Legally Authorized Healthcare Representative. The individual(s) designated by law or the patient (through proper and valid documentation as prescribed by law) to provide consent on behalf of the patient when the patient lacks the Required Age and/or Decision Making Capacity.

NOTE: An instrument that would provide for a Legally Recognized Healthcare Representative that does not meet all the legal requirements (e.g., expired, not properly witnessed, etc) is not valid. Please refer to Surrogate Decision-Maker below.

1. Natural Guardians (When Patient is a Minor)
   a. Parents, as the natural guardians of their children, may provide informed consent for and on behalf of their children under the age of 18. The informed consent of both parents of a minor is desirable; however one parent may provide effective informed consent. If the parents are not married, unless otherwise stipulated by a valid court document, either parent may give consent - the parent with custody of the child or the non-custodial parent. If there are questions between the parents about who may provide the informed consent, please request the custodial order and place in the minor’s medical record.
   b. Minors of any age who have children have the authority to provide informed consent to treatment for those children.
   c. Using a properly executed power of attorney (which should be made part of the minor’s medical record), a Natural Guardian may delegate any of the powers of the parent or legal guardian regarding care, custody or property of the minor child or ward, including health care decision making authority, by a properly executed power of attorney, to the following individuals for the following periods of time:
      i. Another person for no longer than six (6) months
      ii. A School Administrator for no longer than twelve (12) months.
A parent or legal guardian of a minor child may delegate any of the powers of the parent or legal guardian regarding care, custody or property of the minor child or ward, including health care decision making authority, for a period not exceeding the term of active duty service plus 30 days when the parent or legal guardian is a member of the military (active or reserve) who is called to active duty. If the minor child is living with the child’s other parent, delegation under this subsection must be to the parent with whom the minor child is living unless a court finds that such delegation would not be in the best interests of the minor child.

2. Court Appointed Guardian (When Patient is an Adult or Minor)
   a. A court may appoint a legal guardian for an adult or minor. Court appointed legal guardians will have a Letter of Guardianship, which should be obtained and placed in the patient's medical record. This document should be reviewed for any restrictions upon the Guardian’s decision-making ability with respect to making health care decisions for the patient.

3. Healthcare Representative (When Patient is an Adult)
   a. A Healthcare Representative is the person designated by the patient in either an Advance Directive or Healthcare Power of Attorney to make decisions for the patient if the patient becomes incapacitated. Such designated individual may give the informed consent on behalf of the patient lacking capacity by signing the informed consent form in place of the patient. The patient's medical record must have a copy of the Advance Directive of Healthcare Power of Attorney document; these documents should be reviewed for any instructions or restrictions from the patient.

**Material Risk:** A material risk is a risk which a reasonable Qualified Provider knows or should know the particular patient would be likely to consider important, either by itself or in combination with other risks, in deciding whether or not to accept the proposed procedure or treatment. If a serious injury (examples include, but are not limited to, risks such as death, brain damage, organ damage, central nervous system damage, disfiguration, sexual dysfunction, allergic reaction, and irreversibility) might occur from the proposed procedure or treatment, the Qualified Provider should inform the patient of all but extremely remote risks. When a potential injury is slight, the patient need be informed only of common risks.

**Medical Emergency:** when the Qualified Provider believes that the patient potentially suffers from a condition where a clinical decision must be made immediately to prevent death or serious harm to the patient.

   a. Please review “Special Circumstances” below for more information.

**Qualified Provider:** a member of the OHSU workforce acting within the scope of his/her practice to perform the specific procedure or treatment for which informed consent is being obtained. Specifically, one of the following individuals:

   a. an OHSU licensed independent practitioner (physicians, nurse practitioners, dentists) credentialed and privileged to perform the specified procedure/treatment (Online OHSU Practitioner Clinical Privilege View: http://echoapp/echo/echonet/ProviderPortal/msldirP.htm)
   b. a physician assistant privileged to perform the specified procedure/treatment
   c. other clinicians who are licensed, deemed competent and are authorized by the hospital to perform the specified procedure/treatment
   d. those qualified through a residency program to perform the specified procedure/treatment
   e. a dental hygienist privileged to perform the specified procedure/treatment
   f. a dental student deemed competent and authorized by the School of Dentistry to perform the specified procedure/treatment.

**Required Age:** Individuals must reach the required age in order to provide informed consent. These ages are listed as follows (please consult the Legal Department if there are any questions):

   1. Adult patients: Patients 18 years or older.
   2. Minor patients: Patients under 18 years of age who fit within one of the following circumstances/categories:
b. General medical, dental, surgical, hospital treatment provided by a physician licensed by
   the Board of Medical Examiners or a dentist licensed by the Board of Dentistry: age 15
   and above
   i.  [Note: this includes the right to consent to prenatal care]

c. Health care providers may elect, but are not required, to inform the parent of a minor of
   the medical treatment being provided to the minor (except as noted in F(b)(iv) below).

d. Outpatient mental health or chemical dependency treatment: age 14 and above
   i.  [Note: the parent must be notified before the end of treatment unless the parent
        has sexually abused the minor]

e. Birth control information and treatment for sexually transmitted diseases if the disease or
   condition is required by law to be reported to state or local health officers: any age.

f. Emancipated minors of any age are authorized to consent to all forms of treatment
   i.  [Note: emancipation requires a court order to be effective - this document should
        be in the minor’s medical record]

3. Married minors.

**Surrogate Decision-Maker:** If the patient does not have a Legally Recognized Healthcare Representative,
the health care team may contact one of the individuals listed below (in the order listed with reasonable
effort) and ask him/her to provide input into the plan of care or proposed treatment or procedure for the
patient:

1. Patients’ spouse or registered domestic partner
2. Adult child who can be located
3. Either parent
4. Adult sibling of the patient
5. Adult designated by others on this list if no one on the list objects
6. Other adult relative or friend

In this circumstance, the health care team may consider the input provided by the individual(s) listed above
in making a final decision about the treatment or procedure. In making inquiries pursuant to this policy, the
health care team members must be sensitive to the diversity of cultures and familial relationships. The
health care team shall provide care and treatment to the patient based on and consistent with their
understanding of the wishes of the patient expressed prior to incapacity, or if such preferences are unknown,
in accordance with the patient’s best interests. The health care team may ask an individual on the list above
to sign the informed consent form and this form shall become part of the patient’s medical record.

**NOTE:** An instrument that would provide for a Legally Recognized Healthcare Representative that does not
meet all the legal requirements (e.g., expired, not properly witnessed, etc) shall constitute evidence of the
patient’s desires and interests.

**PROCESS FOR OBTAINING INFORMED CONSENT**

Informed consent is required for all procedures and treatments that have viable alternatives and which pose
a Material Risk without regard to whether such procedures are carried out in operating rooms, invasive
diagnostic procedural areas, at the bedside and/or within procedure rooms, including ambulatory care
settings. The following process shall be used.

Informed consent for procedures and treatments will be obtained prior to an episode of care or course of
therapy and is in effect for a period of time as determined by the following:

- Throughout an episode of care;
- Throughout a course of therapy;
- Until the risks or alternatives of the procedure/therapy have changed;
- Until the patient rescinds the consent; or
- Until one (1) year from the date of consent

Only Qualified Providers may obtain informed consent. **The process of obtaining informed consent cannot be delegated to a nonqualified provider.** However, a Qualified Provider not performing the
procedure/treatment may obtain consent from the individual providing consent on behalf of another Qualified Provider. In that instance, the Qualified Provider performing the procedure/treatment is expected to introduce him/herself as the practitioner who will be performing the procedure or treatment and interact with the patient and family prior to procedure/treatment.

Considering that the individual providing consent must:

1. Have Decision-Making Capacity and
2. Have reached the Required Age for the treatment/procedure,

Identify the appropriate individual to provide consent, using the following order:

1. Patient
   a. Continue to (2) below.
   b. **NOTE:** If the patient cannot provide consent, due to not having reached the Required Age, consider first obtaining patient’s assent (permission) before obtaining the Legally Recognized Healthcare Representative’s consent (legally recognized permission).
2. Legally Recognized Healthcare Representative
   b. Confirm valid documentation for individual consenting as Legally Recognized Healthcare Representative is present in patient’s medical record.

**NOTE:** Court Appointed Guardians or Healthcare Representatives cannot consent to the following procedures:

1. Admission/retention in a healthcare facility for care or treatment of a mental illness; except that a health care representative has authority to consent to hospitalization of the principal for a period not to exceed 18 days for treatment of behavior caused by dementia
2. Convulsive treatment
3. Psychosurgery
4. Sterilization
5. Abortion
6. Withholding or withdrawing of a life-sustaining procedure or artificially administered nutrition and hydration, except in specific circumstances.

If any of the above are being considered, call Legal.

1. Continue to (2) below.
2. If neither of the above exists, go to Special Circumstances section of this Policy.

In order to obtain valid informed consent, in accordance with the Centers for Medicare and Medicaid Services’ Conditions of Participation, Oregon Law, The Joint Commission Standards, and OHSU policy, the Qualified Practitioner obtaining the informed consent must do the following:

1. **Procedure/Treatment Plan:** Explain the procedure or treatment to be completed. The explanation should be in general terms the patient can understand and include potential benefits and likelihood of success.
   a. **Document on the form the procedure**, site and/or level. If there are several procedures occurring, you may mark “multiple sites, see above” and indicate the site with each procedure.
   b. **Additional procedures associated with this encounter:** at the bottom of the form is a list of additional processes that you will discuss with the patient. Mark all appropriate boxes and discuss with the patient the risks, alternatives and, if applicable, the benefits of each of these if the professional doing the procedure is credentialed/competent to carry out these processes. These procedures include:
      i. **Transfusion.** If the patient is or may be undergoing transfusion, discuss the Material Risks and alternatives of that procedure and mark the box.
ii. If the patient is only having a transfusion, use the Transfusion Blood Consent Form (HIS Form# CO-1407) and the attached information sheet “What you should know about Blood Transfusion.”

iii. Sedation. If the patient is undergoing sedation, discuss the Material Risks and alternatives of sedation and mark the box.

iv. Anesthesia. For cases with planned anesthesia, mark that box and inform the patient that the Anesthesiologist will discuss anesthesia with the individual providing consent.

v. Vendor Representatives/Observers. If a vendor representative or observer will be present during the procedure, inform the patient of vendor representative/observer presence/roles in the procedure room and mark the box. If the vendor is only present to observe the procedure, the separate patient authorization, Authorization to Use and Disclose Protected Health Information (HIS Form# MR-1470), will be required. Indicate to the patient that the vendor representative performs no part of the procedure.

vi. Vendor representatives are prohibited from engaging in patient care or performing any part of the procedure.

vii. Photos. If photos will be taken for use in treatment, teaching at OHSU, or OHSU’s quality improvement activities, mark that box.

viii. In order to use patient photos for purposes other than patient care, obtaining reimbursement, teaching at OHSU or healthcare operations at OHSU (where operations means certain administrative, financial, legal, and quality improvement activities necessary to run and support OHSU’s business and the core functions of treatment and payment), obtain additional, written authorization from the patient prior to disclosure of any individually identifiable health information about the patient. When patient photographs contain information that identifies the subject individual, complete the form, Authorization to Use and Disclose Protected Health Information (HIS Form# MR-1470). A signed release may also be required if the photo is further published. Note: This authorization must be used if you wish to use patient photos or images that may identify the patient in publications or presentations outside of OHSU.

ix. Additional Practitioners. Inform the patient of specific additional practitioners who will be involved in the procedure or treatment.

2. Alternatives: Discuss alternative procedures or methods of treatment available, including the relevant Material Risks, benefits, and side effects related to alternatives. A general description of these alternatives should be provided including the option of no treatment and possible results of non-treatment.

3. Risks: Explain the planned procedure or treatment, anticipated benefits, Material Risks or potential problems that might occur during recuperation as well as the likelihood of achieving goals. Include the most significant and the most common risks and potential problems related to recuperation.
   a. Documentation of specific risks is not required. However, if the Qualified Practitioner wishes to document any specific risks or concerns discussed, he/she will do so on the blank line, on an additional page, or note the discussion of specific risks in the patient’s medical record.

4. Questions: Ask the patient if a more detailed explanation is desired. If the patient requests further explanation or has questions, disclose in substantial detail the procedure, the viable alternatives and the material risks unless to do so would be materially detrimental to the patient. If the patient does not want a more detailed explanation, or if to give one would be materially detrimental to the patient, none need be given.
   a. Inform the patient of any limitations on the confidentiality of information learned from or about the patient if indicated.

5. Documentation: The informed consent discussion should be documented, signed by the Qualified Practitioner obtaining the informed consent, and by the individual consenting. The Qualified Practitioner should also document the informed consent discussion in the patient’s medical record, stating either “Procedures, alternatives and risks discussed with patient. Questions answered.” OR “PARQ done.”
   1. Written Consent. When a Qualified Provider is required by this policy to obtain informed consent, he/she must make all reasonable efforts to do so in writing using the standard OHSU Healthcare System approved consent form: Patient Informed Consent for Rendering of Medical Services/Surgical Services/Sedation (HIS Form# CO-1400); http://ozone.ohsu.edu/healthsystem/HIS/co1400.pdf - see links to forms in non-English languages at end of this policy).
a. The informed consent form will then be filed in the patient's medical record.
b. Any customized Informed Consent documents must utilize this template and be reviewed and approved in accordance with the policy Medical Record Forms Review and Approval Process (HC-ADM-RPI-P009) prior to use.

2. Telephone consent. Telephone consent should only be accepted and used when there is no reasonable way to obtain written consent and as a last resort. In order to obtain informed consent over the telephone, the following steps must be taken:
   a. The Qualified Practitioner and one other person must be on the line to hear the informed consent.
   b. The Qualified Practitioner and witness receiving the phone consent must identify themselves at the beginning of the phone conversation.
   c. The consenting individual must be specifically asked to identify him/herself and his/her relationship to the patient, including specifying whether the consenting individual has documentation recognizing his/herself as the Legally Recognized Healthcare Representative of the patient.
   d. The Qualified Practitioner will answer all questions prior to completion of the informed consent process.
   e. An appropriate statement describing the conversation and verifying that the proposed procedure/treatment and information on the risks and alternatives must be recorded in the progress notes. The Qualified Practitioner must state who served as the witness to the conversation.
   f. The Qualified Practitioner should complete the informed consent form to document the conversation and the person who witnessed the conversation should sign indicating he/she witnessed the informed consent process and decision.
   g. If the consenting individual is later available, he or she should be asked to co-sign the Informed Consent form. If possible, obtain a confirming telegram, fax or e-mail from the responsible party.

SPECIAL CIRCUMSTANCES

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<th>Situation</th>
<th>Actions</th>
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<tr>
<td><strong>Medical Emergency</strong></td>
<td>Emergency care may be provided under the concept of implied consent, unless we have clear and convincing evidence that the patient would refuse such treatment or procedure (e.g., a DNR order). The ability to provide care under the doctrine of implied consent lasts only so long as the emergency. Once the emergent nature is over, follow the Process for Obtaining Informed Consent outlined above.</td>
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<td>1. Document emergent nature.</td>
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<td>2. Document efforts, if any, to obtain informed consent in progress record.</td>
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<td><strong>Minors where Consent is Refused by Natural or Legal Guardian</strong></td>
<td>In circumstances where a Natural Guardian of a minor patient refuses to give informed consent,</td>
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<td>1. Document the refusal and Natural Guardian’s understanding that staff physicians may be obligated to provide life-saving treatment or blood products to prevent serious, irreversible harm, permanent injury or disability to</td>
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<td>Situation</td>
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<td>the minor patient.</td>
<td>2. Staff physician should notify the Multnomah County Juvenile Court at 503-988-3460 (M-F 8AM-5PM) and ask to speak to someone in the Intake Department regarding an emergency medical court order. After 5PM and on weekends, call 503-988-3489 or 503-988-3475 and ask to speak to someone in the Custody Intake Department regarding an emergency medical court order, after consultation with the OHSU Administrator on Duty, available through the operator.</td>
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<td>3. The Court should be provided with the Natural Guardian’s name, the patient’s name, date of birth, address and phone number, if known, the essential medical information and the problem with consent from the parents or legal guardian.</td>
<td>4. The Court has the authority to override parental refusal, when they refuse to sign the &quot;refusal&quot; form, and provide a court order authorizing necessary, life-saving treatment for the duration of the patient’s admission. If no other issues exist, it is not necessary to take custody of the child. <strong>Consult a hospital pediatric social worker as soon as possible.</strong></td>
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<td>5. The overriding of a Natural Guardian’s refusal is not taken lightly. In circumstances of electivity, persuasion or referral of the case to other medical staff members may resolve concerns. <strong>Contact the OHSU Transfusion Service Director for further information and assistance (503-494-8276 or page through the OHSU operator).</strong></td>
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<td><strong>Adult Patient Lacking Capacity,</strong> <strong>Withdrawal of Life Sustaining Procedure</strong></td>
<td>Refer to policy, <strong>Do Not Resuscitate, Advance Directives, Physician Orders for Life-Sustaining Treatment &amp; End-Of-Life Decision-Making Process, HC-CLN-EXP-P002.</strong></td>
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<tr>
<td><strong>No Legally Recognized</strong></td>
<td>2. Document attempts to identify a Legally Recognized Healthcare Representative and fact that none was found.</td>
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<td>3. Identify potential Surrogate Decision-Maker(s), working with Patient Advocate Office or Social Workers as needed to help locate and/or identify such individuals.</td>
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<td>1. If no one can be identified, located, found to be an appropriate Surrogate Decision-Maker (acting in the patient’s best interest), or willing to consent for</td>
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<td>Situation</td>
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<td>Healthcare Representative</td>
<td>patient, continue to next situation below.</td>
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<td>2. If there is an appropriate Surrogate Decision-Maker identified, proceed with Process for Obtaining Informed Consent, however:</td>
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<td>iii. Obtain input as to how to provide care and treatment based on and consistent with Surrogate Decision-Maker’s understanding of any wishes the patient expressed prior to incapacity or, if patient’s wishes are unknown, in accordance with the patient’s best interest.</td>
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<td>iv. Complete Section B on Informed Consent Form and obtain Surrogate Decision-Maker’s signature.</td>
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<td>v. One attending physician’s signature is required.</td>
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<td><strong>NOTE:</strong> Surrogate Decision-Makers <strong>cannot</strong> consent to the following procedures:</td>
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<td>1. Admission/retention in a healthcare facility for care or treatment of a mental illness; except that a health care representative has authority to consent to hospitalization of the principal for a period not to exceed 18 days for treatment of behavior caused by dementia</td>
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| | 2. Document attempts to identify Legally Recognized Healthcare Representative or Surrogate Decision-Makers, working with the Patient Advocate Office or Social Workers as needed to help locate and/or identify such individuals. |
| | a. This may include obtaining a temporary or permanent guardianship for the patient. |

<p>| | 2. Document attempts to identify Legally Recognized Healthcare Representative or Surrogate Decision-Makers, working with the Patient Advocate Office or Social Workers as needed to help locate and/or identify such individuals. |
| | a. This may include obtaining a temporary or permanent guardianship for the patient. |</p>
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<td>Recognized Healthcare Representative</td>
<td>b. If the patient is developmentally disabled and living in a facility or home licensed as a 24-hour residential service, the patient may be entitled to an Individual Support Plan Team (see OAR 411-365-0120).</td>
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</table>
| No identifiable appropriate Surrogate Decision-Maker | If the patient’s condition requires treatment within approximately 72 hours, then two attending physicians shall complete Section C of the Informed Consent Form prior to performing the procedure or treatment.  
If the patient’s condition does not require treatment within approximately 72 hours, |
|                                       | 1. Continue attempts to identify and locate Legally Recognized Healthcare Representative or Surrogate Decision-Makers.  
2. Refer case to the Clinical Ethics Consult Service for review and recommendations. The Clinical Ethics Consult Service will review all information related to the case and provide advice to the primary care provider.  
3. After the Clinical Ethics Consult Service has provided a recommendation, the Healthcare Team makes a decision on how to proceed.  
   b. Two attending physicians shall sign Section C prior to performing the procedure or treatment. |

Bibliography:

- Oregon Legislative Assembly House Bill 2007
- Oregon Revised Statute 442.015
- CMS Conditions of Participation 482.24(b)(3) and 482.24(c)(2)(v)
- The Joint Commission Hospital Standards

Related Forms:

- "Patient Informed Consent for Rendering of Medical Services / Surgical Services / Sedation" forms:


- **“Transfusion Blood Consent” forms (prints with an information sheet “What you should know about Blood Transfusion”):**

  - **English:** CO-1400
  - **Spanish:** CO-1401
  - **Russian:** CO-1402
  - **Vietnamese:** CO-1403

- **“Transfusion Blood Refusal” forms (prints with an information sheet “What you should know about Blood Transfusion”):**

  - **English:** CO-1407
  - **Spanish:** CO-4609
  - **Russian:** CO-4610
  - **Vietnamese:** CO-4608

- **Medical Record Forms Review and Approval Process (HC-ADM-RPI-P009)**
- **Authorization to Use and Disclose Protected Health Information (HIS Form# MR-1470)**
- **Transfusion Manual**
- **Clin 02/HC-CLN-IHR: Medical Records and Documentation of Care Healthcare System Policies index**
- **Health Information Services Medical Record Forms search**

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**Reviewed:**

36 Months
Author:
Health Information Committee; OHSU Institutional Ethics Committee; Legal Department

Review Committee:
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- OHSU Institutional Ethics Committee
- Legal Department
- OHSU Policy Steering Committee
- Professional Board

Approved By:
Professional Board (clin - adm)

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