GUIDANCE DOCUMENT
Research Protocols and Suicide Risk
Aurora Health Care’s Research Subject Protection Program (RSPP)

The purpose of this guidance document is to assist investigators /study coordinators regarding research proposals that include potential disclosure of suicide risk and to provide guidelines to minimize these risks.

The Aurora Institutional Review Boards (IRBs) view the identification of suicide risk, and the related assessment and intervention for certain types of research projects, as an ethical responsibility of researchers when considering protection of human subjects. In general, for those research protocols involving the elements listed below, the IRBs suggest that the researcher have a viable system for management of subjects identified as having current suicidal ideation.

The IRB understands that research will take place in a variety of settings and thus considers the context of the research procedures. For example, some will take place with limited clinical resources and intervention capabilities, while others will take place in the hospital but in non-behavioral health units, and others may take place in behavioral health units.

Even though we have developed these guidelines, researchers are encouraged to develop procedures, using the general guidelines, and add additional safety measures as applicable to their particular research protocols.

When should potential suicide risk be taken into consideration?
- If questions regarding suicide or harm to self are explicitly part of research-related activities (i.e. part of the testing, interview, or assessment protocol) and are not routinely asked as part of non-research standard of care treatment.
- When the research subject population or research procedures involve elements of depression or suicide risk, such as research on mood disorders, severe mental disorders, self-mutilation, debilitating illnesses, or use of a chemotherapy agent that is known to be associated with an increase of depression.
- Please note that in instances when questions regarding suicide are part of routine standard of care treatment, the IRB would assume that clinical standards are followed in order to protect the safety of the patient.

How do I know if a research subject has the potential to be identified as a suicide risk during the course of my research?
- One scenario includes the intentional identification of suicidal ideation through questions posed during an interview, assessment, or administration of a measurement instrument, such as the Beck Depression Inventory, due to the nature of the research.
- Another scenario is unintentional identification of suicidal ideation through disclosure on the part of subjects in those research projects involving subject populations or procedures that may be associated with mood disorders or debilitating mental or physical illnesses.
- It is also possible that an unintentional identification of suicidal ideation can take place during the course of the research that was not anticipated based on the research procedures and thus a plan is not in place.

What precautions does the IRB expect me to take in order to minimize risk?
- If the IRB anticipates the disclosure of suicidal ideation potentially taking place during the course of the research, the IRB will request that you develop a plan to anticipate and minimize this risk as it occurs.

Version Date 11/3/2008
If a disclosure of suicidal ideation is revealed as part of a research question that is posed, either by interview or questionnaire item, the researcher must be prepared to review and further evaluate a positive response in a timeframe that allows the researcher to take appropriate action to minimize risk with a safe timeframe. It is suggested that any specific questions related to suicide or harm to self be reviewed immediately or as soon as possible, rather than weeks or months after the data collection.

- The IRB strongly encourages that once potential suicidal ideation is disclosed that a risk assessment for that individual is performed by a clinician immediately, including gathering additional information to evaluate the level of imminent danger to self that is present. An adequate assessment of lethality or imminent danger to self should, at minimum, include:
  - Gathering information about the specific thoughts of suicide;
  - Determining whether or not the person has a plan;
  - Determining if the person has the means to carry out the plan;
  - Determining history of suicide attempts, family history of suicide;
  - Obtaining the person’s mental health history, history of use of medication, alcohol or illicit substances that may lead to lowering of inhibitions;
  - Assessing the person’s family or community support system.

- The IRB further recommends that follow-up with the subject is done by a qualified clinician based on the risk assessment to ensure that appropriate actions are taken and subjects are provided with resources in order to minimize this risk.

- If the research subject is in an Aurora hospital, the IRB strongly encourages following Metro Region Nursing Policy – 24 “Suicide Precautions” or a similar policy that may exist in your facility. This policy is attached as an example.

- Procedures for non-clinicians (occurring off site) may include a list of questions to ask in the event of a subject endorsing current suicidal ideation, and the direct contact information for a research clinician or other agreed upon clinician to review the responses to those questions. The clinician can then direct or advise the non-clinician regarding the safety procedure to follow. The procedures would have to include a clinician being readily available in person, or by phone or pager, ordinarily within an hour, for direct consult.

- Ordinarily, giving research subjects a list of referrals or telling the subject to go to a hospital after disclosure or endorsement of seriously thinking about suicide would not be considered sufficient by IRB standards.

- If the person is evaluated as high risk for suicide, the research staff should act quickly to protect the safety of the subject. This may mean staying with the subject until assistance arrives or the person is transported to a hospital.

- For any assessment that indicates less than imminent risk, research clinicians should be available to assist in developing a plan for safety with the subject. The plan for safety will depend on the level of risk and available resources. It may include contacting the person’s personal physician, making sure the subject has appropriate referrals with a plan to contact subjects as a means to evaluate the subject following through with the referrals, encouraging the person to talk to trusted family members or other community support resources, or giving the subject suicide hotline information. Documentation of the assessment and procedures ultimately followed would be important.

**Who can perform the research procedures, risk assessment, and follow-up procedures?**

- In general, this review of the data could be done by anyone who is qualified and trained to do so.

- The IRB may decide on a study-by-study basis whether the suicide-related research procedures should only be conducted by a specific person (e.g., the PI, a clinician).

- If the person collecting the data or conducting the interview is a trained clinician, that is, a psychologist, nurse practitioner, psychiatrist, clinical social worker, or the like, then the clinician can gather their own information and act on the information as clinically indicated, if the clinician has experience with managing suicide risk.

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• If the person is not a clinician or is not familiar with suicide risk management, and the research is taking place in a facility that does not have an established suicide risk protocol, then a system should be in place to gather the necessary information about lethality and/or contact the appropriate clinician or make an appropriate referral for further evaluation and treatment.
• All research staff should be trained on how to assess for suicide risk and the emergency procedures to follow in the event someone is deemed at imminent risk of suicide.
• Clinical research staff should be readily available if the interview or data collection is conducted by non-clinicians or research assistants, either in person, by phone, or pager response, ordinarily within an hour.
• For non-clinicians the response plan should outline procedures for designating and contacting clinicians for guidance, or in the event that the designated clinicians are not available or cannot be contacted (research done off site), procedures for calling 911 to contact police to evaluate the situation and transport the person to the nearest hospital.

**How does this impact informed consent?**
• As disclosure of suicidal ideation may require involvement of clinicians outside of the research, this poses a potential breach in confidentiality. Thus you should inform the subjects about what will happen if they endorse suicidal ideation and, in particular, if they are deemed to be an imminent danger to self.
• This information would ordinarily go in the section of the consent form where you describe the instrument or treatment which may result in disclosure of suicidal ideation.
• The following text is an example: The research staff may not be able to keep confidential any disclosure or endorsement of thoughts to harm yourself. In the event that you tell the research staff that you are thinking about killing yourself or you answer yes to a question about having thoughts about suicide, the research staff will ask you more questions about the thoughts. Depending on how intense your thoughts are or how much you feel like hurting yourself, the research staff may provide you with referrals for treatment, work with you to contact your personal physician, trusted family member, or therapist to discuss your thoughts of harming yourself; or work with you on a plan that may include getting you to a hospital for safety.

**Where should I address suicide risk in the submission application?**
• If your study includes procedures or a population that increases the likelihood of discovering suicidal ideation you should anticipate this risk and develop methods for minimizing this risk and resources that will be provided to subjects. The methods to minimize risk should be described in the Risk-Protection-Benefits section under item B, where you would describe the procedures that are in place to minimize risk that may result due to participating in the research. These should include:
  o A citation of the Aurora Health Care policy you plan to follow, or a detailed description of the plan you have developed.
  o Specific examples regarding the timeframe for reviewing data that may result in potential disclosures of suicidal ideation.
  o Measures for assessing the risk level based on the data collected.
  o Details regarding who will be assessing the risk and their relevant credentials or training they will have to make them qualified to conduct such assessment.
  o A specific action plan should suicidal ideation be apparent, including designating clinicians who will be available, referral lists that will be provided etc.
  o The resources should be described in detail in the Design and Procedures section under item E, where you would describe resources that are available to subjects that they may need as a result of their participation in the study.
• Be sure to answer Section V, Informed Consent, questions A and C in as much detail as possible so the IRB can assess who is conducting the consent process and where it is taking place. As stated above, the IRB may decide that this portion of the research must be conducted by the PI or an appropriate clinician.

Version Date 11/3/2008
Resource List

- The Mental Health Association: 414-276-3122
- Crisis Line: 414-257-7222
- Mobile Crisis Team: 414-257-7621
- Psychiatric Crisis Service: 414-257-7260
- Hotlines-IMPACT 211
- Milwaukee Women’s Center Crisis Line: 414-671-6140
- Aurora Psychiatric Hospital Triage: 414-454-6777
- Aurora Psychiatric Hospital Central Scheduling: 414-773-4312
- Emergency Situations: 911
SUICIDE PRECAUTIONS

PURPOSE:
The purpose of this policy is to respond to the care and safety needs of suicidal/potentially suicidal hospital inpatients on non-behavioral health units; heighten awareness of the staff that the act of suicide is not criminal.

GENERAL INFORMATION:
A. Glossary of Terms - See Appendix A
B. “Suicide Precautions” refers to those actions as continuous 1:1 observation, management of the environment, and safety precautions.
C. This policy and procedure will not replace ICU, ED, or Behavioral Health Department standards.
D. Staff will comply with hospital standards and regulatory guidelines (JCAHO, EMTALA, Wisconsin Chapter 51)

POLICY:
A. The brief Suicide Assessment Form will be used for further evaluation and documentation.
B. Suicide Assessment - Form # X 23937 is accessible on line under “Forms.” The form is bar coded to be copied, completed, and a permanent part of the patient’s record.

Go to: “Forms” on-line, or Click here to go to the form now:
http://ahcweb.aurora.org/forms/Forms/suicide_assessment.pdf

1. A patient is considered at risk for self harm when:
   The patient demonstrates any asterisked characteristics (see A).
   • Verbalization of wanting to die *
   • History of actual suicide attempt *
   • Evidence of self-injurious behavior *
   • Expressions of hopelessness *
   • Verbalization of the inability to cope *

   Three or more non-asterisked characteristics are identified (see A).
   • Acting out behaviors (violence, drug abuse)
   • Increased angry outbursts
   • Change in sleep pattern
   • Change in appetite
   • Increased isolation
   • Change in energy level
   • Change in work/school performance
   • Inability to meet basic needs (ADL’s)
   • Inability to verbalize need for help
   • Somatic responses
   • Inability to make decisions

2. If the patient has answered yes to any of the questions under the suicide dialogue section, a psychiatric consult is needed for further evaluation of suicide risk.

3. If in doubt, err on the side of patient safety and request the consult.
C. A physician order is not needed to initiate suicide precautions.

D. A physician order is needed to discontinue suicide precautions.

E. The Primary Care Provider (PCP) should be notified of the initiation of suicide precautions with requests for psychiatric consultation (to occur within 24 hours).

F. In the event that the primary care provider will not order a psychiatric consult then:
   1. Request PCP to evaluate patient themselves
   2. Consult Manager, CNS/NC, or CNC if PCP is unwilling to evaluate the patient

   Follow decisional chain of command including but not limited to Medical Section Chief.

G. The following policies support this policy:
   1. Metro Administrative Multidisciplinary Clinical Policy manual:
      
      #357 Patient Elopement
      http://ahcweb03.aurora.org/manualmetro/metro_policies/patientelopelementmetro.pdf

      #154 Restraints
      http://ahcweb03.aurora.org/ahcmanual/system_policies/Af000154Restraints.pdf

      #484 Prisoner/Patients
      http://ahcweb03.aurora.org/manualmetro/metro_policies/PrisonerpatientMetro.PDF

   2. Metro Nursing Policy and Procedures:
      
      MN-23 Sitter Policy and Procedure
      http://ahcweb03.aurora.org/metronurse/Policy_and_Procedures/Metro_Nursing_Procedures/MN23_Sitter_Policy_4209_05.pdf

   3. Loss Prevention:
      Policy 023 Weapon Scanner Policy
      Obtain policy from Loss Prevention.

PROCEDURE:

<table>
<thead>
<tr>
<th>ESSENTIAL STEPS</th>
<th>KEY POINTS</th>
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<tbody>
<tr>
<td>1. Patient is placed into 1:1 observation/suicide precaution:</td>
<td>An employee must stay with the patient until arrangements are made for a Level 2 Sitter. (See Metro Nursing Sitter policy - # MN-23 – Click on hotlink above to access Sitter policy now.)</td>
</tr>
<tr>
<td>a. Observer will remain in the same room as the patient while maintaining a safe distance.</td>
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PROCEDURE

<table>
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<tr>
<th>ESSENTIAL STEPS</th>
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<tbody>
<tr>
<td>a. Inform patient of your concerns of risk for self harm</td>
<td>Patient will be restrained only if in the actual act of harming themselves or others (See Restraints policy #154. – Click on hotlink on previous page to access Restraints policy now.)</td>
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<tr>
<td>b. Explain Suicide Precautions to patient.</td>
<td>Family and/or friends are not appropriate for providing any 1:1 observation.</td>
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<tr>
<td>c. Place sign on door “Visitors... Please check in at nurses station.”</td>
<td>See Addendum D for proper signage.</td>
</tr>
<tr>
<td>d. If the patient is reluctant to participate in treatment, dialogue with patient about their concerns re: staying.</td>
<td>Potential resources include CNS, Manager, Chaplain, Social Services, Administration, Physician, and/or Loss Prevention.</td>
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<tr>
<td>e. Refer to Consult Liaison Team (CLT) for psychiatric consult</td>
<td>Physician order required. Call Operator for CLT number.</td>
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2. Patient who has attempted self-harm with a weapon (gun, knife), the police must be called. Loss Prevention may assist with detention in support of Chapter 51.


4. Notify pastoral care, dietary, unit staff, CNS/NC, department manager, and/or CNC of patient having Suicide Precautions initiated.

5. If threat of patient escape or elopement, harming self or others arises, notify Loss Prevention and use recommended strategies.

6. If patient refuses to cooperate with the treatment plan, notify the local police district regarding potential Emergency Detention. Increase patient safety through staff awareness.

7. Prepare the patient’s room:

   a. Nursing, in partnership with Loss Prevention, will search the patient’s belongings for items that could be used for self harm and remove from the room

Examples:
- medications (locked in Pharmacy)
- pocket knife
- matches
- belts
- sharps, such as scissors, razor blades, needles...
- scrub or bathrobe ties
- panty hose or anything that can be used as a noose
- glass objects, (mirrors, makeup bottles)
- non-ingestible liquids (i.e., cleaning agents)
- plastic bags
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<tr>
<td>b. Loss Prevention will participate/document the search.</td>
<td>Confiscated items may be used on a limited basis at the nurse’s discretion and under supervision.</td>
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<td>9. Monitor that patient has actually swallowed medication.</td>
<td>a. Do buccal check if necessary.</td>
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<td>10. Visitors may be limited as requested by the patient or a physician order per policy for safety purposes.</td>
<td>a. Follow existing HIPPA policy.</td>
</tr>
<tr>
<td>11. Sitter is to be present with patient at all times including family/friends visits, physician visits and off-unit testing.</td>
<td>a. Sitter will remain in the room to maintain patient’s safety and also to observe visitor/patient interactions.</td>
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<td>b. Sitter will check belongings/gifts brought to the patient in partnership with loss prevention.</td>
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<td></td>
<td>c. If a physician requests privacy during assessment, sitter will wait outside the doorway until complete.</td>
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<td>12. Discuss with the patient his or her desire regarding visitation by family/friends and what information is to be shared with visitors.</td>
<td>Maintains patient confidentiality and empowers patient.</td>
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<td>13. Obtain activity order from the PCP.</td>
<td>a. Order required for patient to ambulate with sitter on the floor.</td>
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<td>b. Order required for patient to leave the floor accompanied by sitter/security.</td>
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<td>14. Maintain communication and collaboration about care of the suicidal patient with the interdisciplinary team.</td>
<td>Utilize OFT process to include the following discussions:</td>
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<td>• Patient and/or family education related to depression and suicide.</td>
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<td>• Identification of outpatient follow-up care.</td>
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<td>• Assess living arrangements for safety</td>
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<td>• Identification of support system</td>
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## Appendix A

<table>
<thead>
<tr>
<th><strong>GLOSSARY OF TERMS</strong></th>
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<tr>
<td><strong>ACTING OUT</strong></td>
<td>A process whereby an individual engages in negative or maladaptive behavior as an outward response to anger/frustration. Can be aggressive / passive behavior.</td>
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<td><strong>AFFECT</strong></td>
<td>Feeling associated with an action that shows on the face: An emotion or mood associated with an idea or action, or the external expression of such a feeling. Ex: blunted affect.</td>
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<tr>
<td><strong>AFTER CARE</strong></td>
<td>Care for the patient after discharge.</td>
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<td><strong>BUCCAL CHECK</strong></td>
<td>Assessment of the mouth to ensure that the patient has not stored or “cheeked” medications to be used in a potential overdose at a later date.</td>
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<tr>
<td><strong>CHAPTER 51</strong></td>
<td>A legal process that is implemented to protect an individual who is in danger of physical harm to self or others who will not voluntarily seek care and treatment that may be needed for the individual's safety. It is related to a psychiatric condition and in general is not a criminal event. Law enforcement is to attend the patient until their discharge and transfer to the detaining facility, which in Milwaukee County is the Milwaukee County Behavioral Health Department. In practice, the police frequently leave the patients with hospital staff. Statutorily, only law enforcement + Milwaukee County Psychiatrists may lift emergency detentions.</td>
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<td><strong>COBRA</strong></td>
<td>Consolidated Omnibus Budget Reconciliation Act (COBRA) was passed in 1986 with a portion addressing the problem of “patient dumping” — denial of care or transfer of patient based on inability to pay for care. It is a federally mandated standard of practice for hospitals and physicians.</td>
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<td><strong>Depression</strong></td>
<td>A mood disorder that causes people to lose pleasure from daily life. Depression can complicate other medical conditions, and can become serious enough to lead to suicide. Symptoms most commonly include:</td>
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<td>* Persistent sad, anxious or “empty” mood</td>
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<td>* Sleeping too much or too little</td>
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<td>* Reduced or increased appetite and weight loss / gain</td>
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<td>* Loss of pleasure and interest in activities once enjoyed</td>
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<td></td>
<td>* Restlessness, irritability</td>
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<td>* Persistent physical symptoms that do not respond to treatment</td>
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<td>* Difficulty concentrating, remembering or making decisions</td>
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<td>* Fatigue or loss of energy</td>
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<td>* Feeling guilty, hopeless or worthless</td>
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<td></td>
<td>* Thoughts of suicide or death</td>
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<td><strong>Emergency Detention</strong></td>
<td>The detention of an individual in support of Chapter 51. It is related to a psychiatric condition and generally is not a criminal event. Statutorily, only law enforcement + Milwaukee County Psychiatrists may lift emergency detentions.</td>
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<tr>
<td><strong>Energy Level</strong></td>
<td>The ability to do things: the ability or power to work or make an effort</td>
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<td><strong>Euphoria</strong></td>
<td>An exaggerated and intense feeling of physical and mental well-being, especially when not justified by external reality</td>
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<td><strong>Mood</strong></td>
<td>A sustained emotion that can alter one’s whole view of life. Mood is generally used to refer to either elation or depression.</td>
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<td><strong>Police Hold</strong></td>
<td>Relates to criminal charges and the patient being in police custody. In general, if the crime is nonviolent-less serious, law enforcement will leave the patient with us and pick-up upon notification to police that discharge is pending. If it's a serious or violent crime, law enforcement will stay with the patient throughout their hospitalization.</td>
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<tr>
<td><strong>Somatic Response</strong></td>
<td>The conversion of mental experiences or states into bodily symptoms. To believe an emotional pain is a physical symptom.</td>
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<tr>
<td><strong>Suicidal Thoughts</strong></td>
<td>Thinking about harming or killing oneself.</td>
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<tr>
<td><strong>Suicide Risk</strong></td>
<td>At risk for hurting oneself or taking one’s life. Warning signs include:</td>
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<td>* Verbal threats of suicide</td>
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<td>* Expressions of hopelessness and helplessness</td>
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<td>* Previous suicide attempts</td>
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<td>* Daring or risk-taking behavior</td>
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<td>* Personality changes</td>
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<td>* Depression</td>
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<td>* Giving away possessions</td>
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<td>* Lack of interest in future plans</td>
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<td>* Lack of pleasure in life</td>
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6/15/04

### METRO REGION NURSING POLICY/PROCEDURE

O: nurseK\Regpol\Nursing MN\MN-24 – Suicide Precautions 5-06

Effc: 2/02  Revised: 7/02, 3/05, 5/06

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Appendix B: To access this form online: Open the Aurora Intranet home page, type in “Forms” in the box under Search AuroraNet: then click on Forms in the Link Index, click on: “Take me to the forms.” Finally, click on “S” for Suicide.

**SUICIDE ASSESSMENT FORM – SAMPLE FORM**

**Defining Characteristics:** *check all that apply*

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<table>
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<tr>
<td>Verbalization of wanting to die*</td>
<td>Change in energy level</td>
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<td>Previous suicide attempt*</td>
<td>Acting out behaviors (violence, drug abuse)</td>
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<td>Evidence of self-injurious behavior*</td>
<td>Change in work/school performance</td>
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<td>Verbalization of hopelessness*</td>
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<td>Verbalization of inability to cope*</td>
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<td>Increased angry outbursts</td>
<td>Somatic responses</td>
</tr>
<tr>
<td>Change in sleep pattern</td>
<td>Inability to make decisions</td>
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<tr>
<td>Increased isolation</td>
<td>Change in appetite</td>
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</table>

Suicide Evaluation:

I. **History of Suicide Attempts:**
   Self: _______ When _______
   How _______
   Significant Other (friend/family): _______ When _______

II. **Suicide Dialogue:**
   1. “Based on our discussion, I am concerned. Have you had thoughts about harming yourself?”
      Yes____ No____
   2. “Do you have a plan?” Yes____ No____
      If “Yes”: “How would you harm yourself? What would you do? “ “Where would you harm yourself?”

   3. “Do you have the means available to harm yourself?” Yes____ No____
   4. “Do you think your situation is hopeless?” Yes____ No____

III. **Nature of Support System:**

<table>
<thead>
<tr>
<th>Has strong support systems (3 or more people to confide in); strong faith, belief and/or practice; involved in therapy and identified the person as helpful.</th>
<th>Has one person to confide in, but hesitates to do so.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has 2-3 people to confide in (may include professionals).</td>
<td>Has no one they feel they can confide in.*</td>
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<td>Has just one person to confide in and has regular contact with that person.*</td>
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</table>

IV. **Primary Care Physician notified:**
   Response: ____________________________
   Date: __________ Signature: __________
   Printed Name of Signature: __________

**ORDER:** X23937 or go on-line under “Forms” and copy form for proper usage.
Appendix C

NURSING INTERVENTION GUIDELINES FOR
POTENTIALLY SUICIDAL PATIENT WANTING TO LEAVE

1. Ascertain the reason for the patient wanting to leave the hospital. Frequently there is a concrete reason, e.g., worried regarding a relationship, job, children, etc. If this is the case there may be ways to deal with this issue so the patient is willing to stay.

2. Loss Prevention can be called when:
   - The patient is on a chapter 51 hold, Loss prevention is generally authorized to use force to restrain and hold the patient.
   - When the patient is not on Chapter 51, nursing in partnership with Loss Prevention will use alternative tactics to encourage the patient to stay. These interventions include:
     - Discussing options with the patient
     - Explaining what would be in the best interest of the patient
     - Using stalling techniques
     - Offer to call family, friend, or religious representative
     - Detaining a patient in the event of theft, (ie; wearing our gown, monitoring equipment, etc.)
     - Assisting with restraint application
     - If unable to detain, Loss Prevention will contact the police, follow the patient, and supply information to the police.

3. If it is deemed a Behavioral Health consult is needed, talk to the patient and explain why, be compassionate but direct. Explain your concern that they are having suicidal ideation. They may at this point explain further what their plans are.

4. If there is family available, try to gain their support and utilize them to help keep the patient in the hospital. However, you need to assess the situation; the family may agitate the patient further.

5. Ask if they would like to see the chaplain or their own spiritual leader as they are frequently trained in dealing with emotionally distressed persons.

6. Don't make promises that you can't keep regarding issues that are not under your control. For example, it would not be beneficial to tell the patient that if they wait to see the psychiatric consult they "will probably be released."

Appendix D – The following page is a sign to be copied and utilized outside the patient’s room.
Visitors...
Please Check in at Nurses’ Station.
Thank you.
References:

Joint Commission on Accreditation of Healthcare Organizations. Comprehensive Accreditation Manual for Hospitals, the Official Handbook May 2001 Revision; Published by Joint Commission Resources, Inc., USA.


