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| |  |  |  | | --- | --- | --- | | **Huron Perth Healthcare Alliance** | | | | **Patient Care** | Original Issue Date: | March 30, 2001 | | **Consent for Treatment** | Review/Effective Date: | January 29, 2021 | | **Approved By: President and CEO** | Next Review Date: | January 29, 2023 | |
| https://intranet.hpha.ca/myalliance/imgs/spacer.gif |
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| |  | | --- | | **POLICY:**  In keeping with the Health Care Consent Act (1996) (HCCA), informed consent to treatment is required from all patients or their substitute decision-maker (SDMs) for all acts and procedures as defined in this policy administered by healthcare practitioners.  Consent is a process based on effective communication and a trusting relationship between the healthcare practitioner proposing the treatment and the patient.  It is important for the healthcare practitioner to be satisfied that the patient has provided a valid informed consent, meaning that a patient receives information from a healthcare practitioner concerning the proposed treatment, procedure or intervention; risks and benefits of the proposed treatment and those associated with not consenting to the treatment; and has an opportunity to ask questions arising from the explanation.  The following elements of consent must be present for consent to be valid:  A. Consent must be related to treatment  B. Consent must be informed  C. Consent must be voluntary (not obtained through fraud or misrepresentation)  D. The person giving consent must be capable of comprehending the decision to either consent to or refuse treatment  Under this policy pursuant to defined acts and procedures, an additional requirement is for a consent form to be signed by the patient or SDM for those procedures outlined in [Appendix C- Treatments, Procedures and Interventions Requiring Written consent at HPHA](https://intranet.hpha.ca/myalliance/doc.aspx?id=7948) (refer to HPHA Consent for Treatment, Surgical Operation, Procedure or Diagnostic Test, Forms Online AD0012).  Where required, patients will be asked to sign appropriate Hospital documents to signify that they have received the relevant information and have had an opportunity to have all their questions with respect to treatment answered.  The Huron Perth Healthcare Alliance (HPHA) recognizes that a consent form signed by a patient does not in itself provide the organization or the healthcare practitioners with conclusive proof that the patient has provided an informed consent. The conversation between the patient and the healthcare practitioner is the essence of the process of obtaining consent; the signed consent document merely provides evidence of the fact that the consent process took place and is not to be considered consent itself.  **PURPOSE:**  The purpose of this policy is to ensure practices at the HPHA meet the legislative requirements of all professional health regulatory colleges, promote patient autonomy, and guide the provision of ethically sound care.  **DEFINITIONS**:  [Appendix A - Definitions](https://intranet.hpha.ca/myalliance/doc.aspx?id=7950)  **PROCEDURE:**  **1. Obtaining Consent**  Informed consent must be obtained through discussion between the Healthcare Practitioner proposing the treatment and the patient, or the patient’s Substitute Decision Maker (SDM), in which the healthcare practitioner provides all the necessary information to the patient regarding the proposed treatment and answers the patient’s questions about the particular proposed plan of treatment.  The healthcare practitioner shall obtain informed consent from the patient if he/she is capable with respect to the treatment. In the event that the patient is incapable, informed consent shall be obtained from an SDM according to the hierarchy set out in the Health Care Consent Act and this policy (refer to  [Appendix B - Substitute Decision Maker (SDM) Hierarchy](https://intranet.hpha.ca/myalliance/doc.aspx?id=7949" \t "_blank)).  **NOTE:** In the event that the patient is incapable and there is no SDM as defined under the Substitute Decision Maker Hierarchy in the *Health Care Consent Act,* the Public Guardian and Trustee (PGT) will be notified to assume responsibility for the patient’s treatment decisions. If an individual, age 16 years or older, who is not defined under the SDM Hierarchy is available and willing to act as the patient’s SDM, they are required to submit a [Form C – Application to the Board to Appoint a Representative under Subsection 33(2), 51(2) or 66(2) of the *Health Care Consent Act*](http://www.forms.ssb.gov.on.ca/mbs/ssb/forms/ssbforms.nsf/FormDetail?OpenForm&ACT=RDR&TAB=PROFILE&SRCH=1&ENV=WWE&TIT=form+b+capacity&NO=014-2976-04E) to the Consent and Capacity Board who will conduct a hearing to determine if the individual may act as the patient’s representative. Until such time as a representative is appointed by the Consent and Capacity Board, the PGT would act in this capacity for the patient.  **Note:** In the event that a newborn or paediatric patient does not have a SDM, the Most Responsible Physician will direct treatment decisions, emergency or otherwise, until a SDM is identified.  **NOTE: Nurses or other Health Professionals are not permitted to obtain consent for a prescribed medical or surgical treatment, procedure or intervention unless certified to do so (e.g. PICC line insertion).**  Consent is considered informed when the following components have been discussed and where consent has been obtained voluntarily and without misrepresentation or fraud.   * the nature of the treatment(s) * the expected benefits * the material risks and side effects * alternative courses of action * the likely consequences of not having the treatment(s)   **NOTE**: There is no age of consent. A person of any age can provide informed consent if the practitioner proposing the treatment is of the opinion that the individual understands the information provided and appreciates the consequences of the decision.  **2. Assessing Capacity**  There is a legal presumption that all patients are capable unless there are reasonable grounds to believe otherwise; a patient’s capacity to consent to treatment can change throughout the course of their hospitalization (College of Nurses of Ontario, 2017; College of Physicians and Surgeons of Ontario, 2015). A patient may be capable to consent to some treatments, procedures or intervention but not others.  A patient is considered to be capable where the individual is able to understand the information that is relevant to making an informed decision with respect to the proposed treatment, procedure or intervention and is able to appreciate the foreseeable consequences of a decision or lack of decision (section 4(1) HCCA, 1996).  A healthcare practitioner shall not presume that a patient is incapable based on any of the following:   * the existence of a psychiatric or neurological diagnosis * the existence of a disability, including a speech or hearing impairment * a refusal of a proposed treatment that is contrary to the advice of the healthcare practitioner or of another person * a request for an alternative treatment * the patient’s age   Assessing capacity is the responsibility of the healthcare practitioner proposing the treatment and occurs during the discussion of proposed treatment(s) with the patient. Healthcare practitioners shall use, to the best of their ability, a means of communication which takes into account the patient’s education, age, preferred language, cultural and special needs as required.  In cases where the patient is considered to be incapable of consenting to treatment, the patients SDM may provide or refuse consent on the patient’s behalf based on the patient’s previously expressed wishes if known or values.  **3. Managing Incapacity**  Where a healthcare practitioner determines that a patient is incapable with respect to providing informed consent for a proposed treatment, procedure or intervention, the healthcare practitioner will inform the patient of their finding of incapacity and will provide the patient with information about the consequences of the findings (i.e., that the patient may apply to the Consent and Capacity Board for a review of the finding of incapacity) and/or for the appointment of a personal representative of the patient’s choice.  The healthcare practitioner will inform the patient that the SDM will be sought to provide or refuse consent on the patient’s behalf based on the patient’s previously expressed wishes if known or values.  **4. Emergency Treatment without Consent**  A treatment may be administered to a person who is incapable with respect to the treatment if, in the opinion of the practitioner proposing the treatment **ALL** of the following four conditions are present:   * the person is apparently experiencing severe suffering, or * the person is at risk of sustaining bodily harm if the treatment is not administered promptly * the person is mentally incapable of making a treatment decision * A SDM cannot be located in time provided all conditions above are present   Communication Barrier  Emergency treatment without consent may be provided to a person who is apparently capable but the communication needed to get consent or refusal cannot take place in a timely fashion because of a language barrier or disability. Steps that are reasonable in the circumstances must be taken to find a way for the communication to take place and there must be no reason to believe that the person does not want the treatment.  Prior Wishes  A healthcare practitioner cannot administer emergency treatment, procedures or interventions if he/she is aware that the person, while capable, expressed a wish not to have the proposed treatment, procedure or intervention.  Continuing Efforts to Get Consent  Where treatment is begun in one of the above situations, the healthcare practitioner must ensure that all reasonable efforts are continued to contact a SDM. Once the emergency phase has ceased, the patient must be made aware of all of the treatments, procedures or interventions they received, including the administration of blood and/or blood products.  Emergency treatment may only be continued without consent for as long as it is reasonably necessary to mitigate patient suffering, decrease the risk of sustained bodily harm and while the patient is mentally incapable of decision making until an SDM can be located to obtain consent to, refusal of, or the continuation of treatment.  **5. When is written consent required?**  Not all treatments require written verification of a signed consent. HPHA requires that the healthcare practitioner proposing the treatment(s) obtain signed evidence of formal consent with the completion of all sections within the HPHA Consent for Treatment, Surgical Operation, Procedure or Diagnostic Test (Forms Online AD0012) for the treatments, procedures or interventions outlined in [Appendix C- Treatments, Procedures and Interventions Requiring Written consent at HPHA](https://intranet.hpha.ca/myalliance/doc.aspx?id=7948) from the patient or SDM.  **NOTE: If there is any doubt that a written consent is required, obtain a written consent**  **NOTE:** Abbreviations must not be used when describing the treatment, procedure or intervention on the consent form  **6. Who Obtains the Written Consent?**  The healthcare practitioner proposing the treatment is responsible for ensuring that the patient/SDM has provided informed consent prior to the treatment. This healthcare practitioner has the most knowledge to fully explain and answer questions relating to the risks, benefits and alternative treatment options available to the patient.  Written consent may be obtained by a physician, therapist, nurse or technician as long as they are the proposer of the treatment and are permitted according to their respective college regulations and/or the Regulated Health Professionals Act (RHPA) to propose the treatment, have the knowledge to obtain an informed consent and are able to answer a person’s questions about the treatment.  **NOTE**: It is important that the HPHA Consent for Treatment, Surgical Operation, Procedure or Diagnostic Test (Forms Online AD0012) be signed by the patient or SDM at the time that the healthcare practitioner proposing the treatment discusses the proposed treatment with the patient.  For the purposes of providing treatment at the HPHA, the healthcare practitioner proposing the treatment must show evidence of express informed consent by providing the hospital with a completed hospital consent form signed by the patient/SDM (HPHA Consent for Treatment, Surgical Operation, Procedure or Diagnostic Test, Forms Online AD0012). A physician may obtain written consent in his/her office/clinic for in/out patient treatments. The signed consent must be included in the patient’s medical record.  **7. Documentation of Consent Discussed by Healthcare Practitioners Proposing Treatment**  In addition to obtaining the written consent form, the healthcare practitioner is also responsible for documenting details relative to the consent process in the patient electronic health record. These details should include:   * The healthcare practitioner’s opinion about the patient’s capacity to consent to the proposed treatment * When the discussion occurred * Who was present during the discussion * The name of the healthcare practitioner obtaining consent * Details regarding the information provided to the patient/SDM and any concerns or questions expressed by the patient/SDM * Who provided the consent to treatment * Where applicable, confirmation that the patient/SDM received written information regarding the treatments, procedures or interventions * If the patient/SDM had any questions and the answers provided to those questions   **8. Witnessing and Third Party Signatures**  There is no legal or professional standard (CNO, CPSO) requiring a consent form to be witnessed. The patient, after providing informed consent, is required to sign the acknowledgement section of the consent to treatment form. This signature by the patient provides written evidence that a discussion about a proposed treatment, procedure or intervention took place.  For surgical, invasive or non-surgical procedures that carry a risk of harm to the patient, it is recommended that the healthcare practitioner proposing the treatment, procedure or intervention document the consent process in the patient’s medical record.  **9. Telephone/Fax/E-mail/Physical Inability to Sign Consent**  If the patient is unable to sign their name, they may make a mark (e.g. “X”) on the consent form that is recognized as the patient’s own identifier in place of a signature.  **NOTE:** If the patient or his/her SDM is unable to sign the form due to a physical disability, then the signature of a regulated health professional as a witness is required on the consent form. The patient, if capable, or the SDM, should indicate verbal agreement to the treatment in the presence of the healthcare practitioner proposing the treatment and a witness.  The witness must print their name and professional designation, sign their name and write the date on the consent form indicating they confirm that consent was given to the healthcare practitioner proposing the treatment.  In addition to signing the consent form, this verbal consent should be documented in the notes of the healthcare practitioner proposing the treatment and in documentation completed by the witness.  **Note:** If consent is obtained in the healthcare practitioner’s office and the patient is unable to sign the form, the health care practitioner is to have a witness sign the consent form after the patient, if capable, or the SDM indicates verbal agreement to the treatment in the presence of the healthcare practitioner proposing the treatment and a witness.  Telephone, Fax/Email consents are acceptable; however it is preferred that consent be obtained in person where possible. If consent is obtained through fax/email, the copy of the consent must be included in the patient’s medical record. The patient/SDM should be encouraged to forward the original signed consent to the requesting healthcare practitioner to be included in the patient’s medical record.  If a patient is not capable to sign his/her consent form, telephone consent from the SDM may be obtained. The healthcare practitioner proposing the treatment, procedure or intervention is responsible for completing section B of the consent form. Appropriate identification of the SDM over the phone is accomplished through verbal confirmation by the healthcare practitioner obtaining consent.  **10. Duration of the Consent**  The Health Care Consent Act places no restriction on time frame for the validity of a signed consent form. Unless the patient explicitly states that his/her consent is being withdrawn, there is a presumption that the patient’s consent is still in force and that there is no need to explicitly verify it.  Consent is valid until:   * The treatment for which consent has been provided is performed * The patient’s condition changes (e.g. capacity or acute illness requiring different treatment) * The patient withdraws the consent * Further risks become known, or alternative treatments become available.   In the event that more than one month’s time has passed from obtaining consent to providing the treatment, procedure or intervention, it is strongly recommended that the healthcare practitioner reconfirm that the patient has had the treatment, procedure or intervention fully explained and had an opportunity to ask questions.  In the event that more than one year (or 6 months for consent for the administration of blood products) has passed from obtaining consent to providing the treatment, procedure or intervention, healthcare practitioners are advised to obtain a new consent form and document the process.  For outpatients, the informed consent is considered valid for the plan/course of treatment/services provided. It is advised that the consent be reviewed on a yearly basis for this patient group.  **11. Age of Consent**  There is a presumption in the HCCA (1996) that every individual is capable unless there are reasonable grounds to believe otherwise. There is no minimum age for providing consent to treatment in Ontario. If, in the judgment of the healthcare practitioner proposing the treatment, the patient has been determined to have capacity to understand the nature and consequences of the treatment decision, the patient is legally permitted to provide her/his own consent.  A minor who is a ward of a Children’s Aid Society or for whom a guardian has been appointed has all the rights a child would have if living with her/his parents. The organization or guardian having custody of the child has the same right, duty and responsibility as a parent. Therefore, a minor in such circumstances may consent to treatment just as any other minor might do.  **Note:** The healthcare practitioner is advised to take care when evaluating the capacity of a young patient especially in cases where the procedure presents greater risk. In these scenarios, the healthcare practitioner may consider seeking a second opinion from another physician.  **12. Patient has Received Medication that Affects the Central Nervous System**  The patient can consent to the proposed treatment provided that he/she;   * does not exhibit a decrease in level of consciousness * is not confused * is not disoriented as a result of the medication or agents   If any of the above is present, treatment must be postponed until the patient is deemed capable to consent with respect to the proposed treatment. If this delay would precipitate emergency conditions, efforts should be made to contact a SDM as possible before proceeding.  **13. Prior Capable Wishes and Advance Directives**  Prior Capable Wishes are instructions regarding the type of treatments or procedures that a capable person who is at least 16 years of age would or would not want to receive in various situations. These wishes may be expressed orally or in writing or in any other medium (e.g. video).  For the purposes of this policy, a document or recording expressing a patient’s prior capable wishes is called an Advance Directive or Advance Care Plan. If available, a copy of this document should be placed in the patient’s chart.  If a situation arises and the patient is deemed incapable and the SDM is directing the care in a way that is in contravention of the Advance Directive the following resources are available:   * The Manager and Director of the area involved * The Medical Program Director responsible for the program involved * A consult with the Hospital Ethicist or member of the HPHA Ethics Committee   **Note**: The Prior Capable Wishes expressed through an Advance Directive are only binding on a Substitute Decision Maker if the person is 16 years of age or older. If a person under the age of 16 years has purported to make an advance directive regarding their care while capable and becomes incapable, the person’s advance directive does not hold the same legal force as the wishes of a patient 16 years of age and older, and the SDM is called upon to give or refuse consent in accordance with the principles in section 21 of the HCCA. See [Appendix A - Definitions](https://intranet.hpha.ca/myalliance/doc.aspx?id=7950) in regards to the criteria the SDM is to take into consideration when determining to give or refuse consent.  **14. Withdrawing Consent**  The principles of consent also include the patient’s right to withdraw consent. The patient or SDM, in the case of an incapable patient, has the right to withdraw consent at any time. The withdrawal of consent should be noted in the patient’s medical record and on the consent form. No treatment may be administered once the consent has been withdrawn.  **15. Refusal of Consent**  Refusal of Treatment by Patient  Capable patients have the legal right to refuse treatment.  There is a basic premise in law and policy, which states that any patient of sound mind has the ethical and legal right to refuse the most essential treatment at any time, before or during the course of treatment.  As with any consent process, the healthcare practitioner should engage the patient/SDM in discussion in an attempt to obtain informed consent. Where the patient refuses to provide consent, the healthcare practitioner should be satisfied that the patient is aware of the consequences of refusing treatment including an awareness of the risks and benefits of the proposed treatment being declined, and the risks of no treatment.  If the patient continues to refuse the treatment, procedure or intervention, the refusal must be documented in the patient's medical record.  Refusal of Treatment by Substitute Decision-Maker  A Substitute Decision Maker has a right to refuse treatment on behalf of the incapable person. However, if the SDM refuses treatment on an incapable person’s behalf the treatment may still be administered if, in the opinion of the healthcare practitioner proposing the treatment:   * There is an emergency   AND   * The SDM did not comply with the requirements set forth in the Health Care Consent Act.   In non-emergent situations the healthcare practitioner may apply to the Consent and Capacity Board for a review to determine whether the SDM acted in the best interests of the patient.  An SDM may only give or refuse consent if they are:   * capable * sixteen (16) years old (unless he or she is the incapable person’s parent) * is not prohibited by a court order or separation agreement from having access to the incapable person * is available and willing to assume the responsibility of giving or refusing consent   **NOTE:** With respect to a parent declining Erythromycin eye drops for the newborn, the following steps must be followed:   * parent’s request **must** be in writing (only one parent is required to request) * request will be granted by healthcare professional (e.g. physician, nurse, midwife) attending birth **IF**   \* the parent of the child making the request has received information on the risks and benefits of administration of the eye drops as well as information regarding the likely consequences of the non-administration of the eye drops (informed consent) and  \* an assessment has been completed by a regulated healthcare professional to confirm there is no serious risk to the child of an infectious agent that might cause opthmalmia neonaturum   * the written request is included in the newborn’s medical record * the healthcare professional granting the request documents that the parent received information regarding risks, benefits, and likely consequences and an assessment to confirm there is no serious risk to the child has been completed.   **NOTE:** With respect to the Patient Source for suspected Hepatitis B, Hepatitis C and HIV not consenting to testing**,** refer to [HPHA Needle Stick Injury or Blood/Body Fluid Exposure Surveillance Protocol for Staff and Patients policy](https://intranet.hpha.ca/myalliance/Default.aspx?cid=1534&lang=1).  **16. Jehovah’s Witnesses**  The use of blood or blood products as a therapeutic treatment contravenes the belief structure of Jehovah’s Witnesses.  Healthcare practitioners have a responsibility to respect a patient’s right to autonomous decision making even if this causes an ethical and/or moral dilemma within the healthcare practitioners’ beliefs and values.  Where a patient’s religious belief is not in keeping with treatment options involving blood and/or blood products, the patient will not under any circumstances, including emergency situations, receive blood and/or blood products and any alternative treatment options offered must be discussed and documented in the patient’s medical record.  **17. Blood and Blood Product Administration**  There are informed consent requirements that apply specifically to the administration of blood or blood products that are not fulfilled by routine hospital admission consent forms (Health Canada, 2004). Each patient undergoing a transfusion of blood and/or blood products must provide his/her consent or refusal to undergo transfusion and this must be documented on the Consent for Administration of Blood Products at HPHA SITE form (Forms Online LB0002M2).  Responsibility for obtaining informed consent for blood and/or blood products rests with the healthcare practitioner proposing the treatment.  As per the *Krever Commission Interim Report,* it is strongly recommended that the treating physician obtain informed consent from the patient while ensuring that the patient is informed of the risks and benefits of, and alternatives to, allogeneic blood transfusion. The Consent for Administration of Blood Products at HPHA SITE form (Forms Online LB0002M2) is to be completed by the healthcare practitioner and signed by the patient or SDM. (Consent for Administration of Blood Products at HPHA SITE form, Forms Online LB0002M2).  Surgical Procedures  A Type and Screen (TS) ordered for any surgical procedure indicates that there is the potential that blood and/or blood products may be administered during the surgical procedure. It is recommended that the patient be informed and provide consent for blood transfusions in advance of the surgical procedure (except in emergency cases when the patient is unable to consent).  The Consent for Administration of Blood Products at HPHA SITE form (Forms Online LB0002M2) is to be completed by the healthcare practitioner and signed by the patient or SDM. (Consent for Administration of Blood Products at HPHA SITE form, Forms Online LB0002M2).  If during the course of the surgical procedure blood and/ or blood products are administered, the patient must be informed that they did in fact receive these products. This is part of the complete informed consent process.  Ongoing Transfusion Therapy  A patient for whom regular transfusion therapy forms a part of their treatment plan may give his/her consent to transfusion therapy and this consent shall be valid for any/all of the following:   * for the duration of the ongoing transfusion therapy * until 6 months has passed * the treatment plan is altered. * until the patient’s status has changed (i.e. patient is admitted)   **18. Patients’ questions or concerns**  Where a patient has questions or expresses concerns about a planned treatment, procedure or intervention for which they provided prior consent, the attending physician or proposer of the treatment must be notified immediately with the treatment, procedure or intervention being delayed until the patient’s questions or concerns have been addressed.  **19. Language Barriers**  If a patient or SDM is unable to understand or communicate clearly with the healthcare practitioner due to a language barrier, every attempt shall be made to communicate with the patient or SDM in their preferred language through the use of a qualified interpreter via phone or face to face.  Where possible, it is advised that the use of family members as interpreters should be avoided.  **Appendices:**  [Appendix A - Definitions](https://intranet.hpha.ca/myalliance/doc.aspx?id=7950)  [Appendix B - Substitute Decision Maker (SDM) Hierarchy](https://intranet.hpha.ca/myalliance/doc.aspx?id=7949)  [Appendix C- Treatments, Procedures and Interventions Requiring Written consent at HPHA](https://intranet.hpha.ca/myalliance/doc.aspx?id=7948)  **Appendix D**: HPHA Consent for Treatment, Surgical Operation, Procedure or Diagnostic Test, Forms Online AD0012  **References:**   * <https://www.cpso.on.ca/uploadedFiles/policies/policies/policyitems/Consent.pdf> * Canadian Medical Association Journal. 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Commission of Inquiry on the Blood System in Canada (Krever Commission). Available at: <http://www.hc-sc.gc.ca/ahc-asc/activit/com/krever-eng.php> * Health Care Consent Act, 1996. (1996). Ontario Regulation 856/93. Retrieved June 15, 2018. Available at: <https://www.ontario.ca/laws/statute/96h02?search=e+laws#BK17> * Hotel Dieu Grace Healthcare. Clinical Policy – consent for Treatment/Services. * HPHA Policy 3.1.1 Blood-Blood/Blood Product Utilization Guidelines * HPHA Policy 3.1.2 Blood-Blood/Blood Product Verification, Request and Monitoring * Appendix B Blood and Blood Products Requiring Written Consent * Appendix D Consent to Blood Transfusion/Manufactured Blood Products * Quinte Healthcare Corporation. Administration Manual – Consent for Treatment. Policy no. 2.10.3May 2014. * Quinte Healthcare Corporation. Resource Manual – Blood and Blood Product Administration * Regulated Health Professions Act, 1991. Retrieved June 15, 2018. https://www.ontario.ca/laws/statute/91r18 * Substitute Decisions Act, S.O. 1992, c. 30. <https://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_92s30_e.htm>. Retrieved June 15, 2018. * Winnipeg Regional Authority – Informed Consent (for Procedures, Treatments and Investigations). January 2015 policy number 110.000.005. | |