

Clinical Manual Policy

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PREAMBLE

Informed consent to treatment refers to the process by which patients are provided information necessary to meaningfully exercise their right to make their own decisions about their healthcare. The principle of informed consent is based upon a person’s right to be free from bodily harm or interference, as well as their right to autonomy in healthcare decisions. Section 54(1) of the Nova Scotia *Hospitals Act* states: "No person admitted to a hospital or a psychiatric facility shall receive treatment unless he consents to such treatment."

In order to recognize and protect these rights and to comply with governing legislation and professional standards, it is imperative that all treating healthcare providers implement the elements of informed consent before providing any treatments.

This policy describes the steps for obtaining consent to treatment in accordance with the law and governing best practice; however, professional judgment is always required. Specific determinations about when and what form to use must be determined by the relevant healthcare teams in light of the nature of the care/treatment provided.

GUIDING PRINCIPLES AND VALUES

1. All patients with capacity have the right to determine what is done to their bodies, and should participate in consent decisions to the extent of their capacity to do so.
2. Patients who do not have capacity to consent to a specific decision shall be represented by their legally authorized substitute decision-maker.
3. Informed consent is an ongoing process; it is not a form. A signed consent form is helpful documentary support, but does not prove that informed consent to treatment was obtained.

POLICY

1. **NEED FOR CONSENT TO TREATMENT:** The treating healthcare professional must recognize the need for consent prior to administering any treatment.
 - 1.1. In many interactions in the Health Centre, **implied consent** is appropriate or **verbal consent** is appropriate. The behavior/words of a patient, and the circumstances in which the patient is being seen, are often sufficient for the treating healthcare provider to infer consent for no-risk or minimal-risk routine procedures. Examples of **implied consent** include: cooperating with a physical examination; holding out an arm for venipuncture; participating in a physiotherapy consultation. Routine but potentially physically or emotionally

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uncomfortable interventions should generally prompt a request for **explicit verbal consent**. For some patients, the treating healthcare provider may anticipate that verbal consent will be helpful for any physical contact, no matter how seemingly routine.

- 1.2. The *General Patient Care Consent* and *General Consent for Newborn Care* form must be used for inpatient routine low-risk care such as personal care, examination, assessment, medication administration, and routine diagnostic investigations such as bloodwork.
 - 1.3. The *Consent to Treatment and Investigative Procedures* form, a purpose-specific form, or in that treating healthcare provider's progress notes in the health record must be used to document the more specific discussion of informed consent (according to the Elements of Informed Consent, Section 4, below).
 - 1.4. Healthcare providers must recognize a patient's right (or SDM's right) to refuse any treatment, even no-risk or minimal-risk routine care. Please see Refusal of Consent, Section 5, below.
2. **WHO OBTAINS CONSENT:** The treating healthcare provider, i.e. the clinician providing the proposed treatment is the person who must ensure informed consent is obtained. The treating healthcare provider may delegate the responsibility for obtaining consent if and as appropriate, and consistent with applicable professional standards/guidelines, but only to a comparably qualified designate.
 3. **WHO PROVIDES CONSENT:** The treating healthcare provider must identify the person (the consent giver) with whom the informed consent discussion should take place.
 - 3.1. When the patient has capacity (see Elements of Informed Consent, Section 4, below) to make the decision about the proposed treatment, the consent giver is the patient. No one other than the patient may consent/refuse consent to treatment on behalf of a patient who has capacity.
 - 3.1.1. In a family-centered care setting, the consent process would normally involve consultation with the patient's family, but this can only occur with the patient's permission.
 - 3.2. When the patient does not have capacity to make the decision about the proposed treatment, the treating healthcare provider must inquire whether the patient has a valid Personal Directive in place. Personal Directives are written documents, defined and legislated under the Nova Scotia *Personal Directives Act*.
 - 3.2.1. If such a personal directive exists and names a *delegate* for healthcare decisions, this delegate will act as the patient's Substitute Decision-Maker, and must act in compliance with the instructions set out in the personal directive.

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- 3.2.2. If a personal directive exists but it does *not* name a delegate, the patient's SDM must be identified in accordance with the statutory list described in section 3.3 below. The treating healthcare provider and SDM must ensure treatments provided are in compliance with the instructions or principles specified in the directive.
- 3.3. When the patient does not have capacity to make a decision about the proposed treatment, and no delegate is named in a personal directive, the treating healthcare provider must identify the appropriate **Substitute Decision Maker (SDM)** from the statutory list set out below.

The patient's SDM shall be the person ranking in the highest priority, based on the following order, who has capacity and is willing to act:

- I. a person authorized by the patient to act as their 'delegate' in a personal directive, made in accordance with the *Personal Directives Act*;
- II. the patient's court appointed guardian;
- III. the spouse of the patient;
- IV. an adult child of the patient;
- V. a parent of the patient;
- VI. a person who stands *in loco parentis* to the patient;
- VII. an adult sibling of the patient;
- VIII. a grandparent of the patient;
- IX. an adult grandchild of the patient;
- X. an adult aunt or uncle of the patient;
- XI. an adult niece or nephew of the patient;
- XII. any other adult next of kin of the patient;
- XIII. the Public Trustee.

3.3.1. The SDM has the right to be provided with all information and records pertaining to the patient that are relevant to the consent decision for the proposed treatment.

3.3.2. As needed (e.g. in cases where there has been confusion/dispute about who will be acting as SDM), once the SDM is identified and confirmed, before acting, the **SDM** shall make a statement in writing (**Declaration of SDM Form**) certifying as follows:

- I. the person's relationship to the patient; and
- II. excepting a spouse, that they have been in personal contact with the patient over the preceding twelve-month period or has been granted a court order to shorten or waive the twelve-month period; and
- III. that they are willing to assume the responsibility for consenting to or refusing consent; and

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- IV. that they know of no person of “higher category” from the list above who is able and willing to make the decision.

The **SDM** must make decisions on the patient’s behalf in accordance with the patient’s prior capable informed express wishes **unless**:

- a) there were expressions of a contrary wish made subsequently by the maker when the maker had capacity;
- b) technological changes or medical advances make the prior expressed wishes inappropriate in a way that is contrary to the intentions of the patient; or
- c) circumstances exist that would have caused the patient to set out different instructions had the circumstances been known based on what the SDM knows of the values and beliefs of the patient and from any other written or oral instructions.

In the absence of awareness of a prior capable informed expressed wish, the **SDM** must make decisions in accordance with what he/she believes the wishes of the patient would be based on what the **SDM** knows of the values and beliefs of the patient and from any other written or oral instructions.

If the **SDM** does not know the wishes, values and beliefs of the patient, the **SDM** must made decisions in accordance with what he/she believes to be in the “**best interests**” of the patient. When determining what is in the patient’s “best interests”, the SDM must consider whether;

- I. the patient’s condition will be, or is likely to be, improved by the specified medical treatment;
- II. the patient’s condition will improve, or is likely to improve, without the specified medical treatment;
- III. the anticipated benefit to the patient from the specified medical treatment outweighs the risk of harm to the patient; and
- IV. the specified medical treatment is the least restrictive and least intrusive treatment that meets the requirements of clauses i, ii, and iii

4. **ELEMENTS OF VALID INFORMED CONSENT:** Once the appropriate consent giver has been identified, the treating healthcare provider must ensure that the consent process is valid. The validity of consent rests on whether each of these four elements of consent are met:

- 4.1. **Voluntary:** Consent must be voluntary. The decisions must be free of undue influence and coercion, or misrepresentation regarding the nature of the treatment.
- 4.2. **Capacity:** The consent giver (either the patient or, if applicable, the SDM) must have capacity to consent. Adult patients (19 years and older) are presumed to have capacity; however, there is no legislation in Nova Scotia defining a minimum age of consent for healthcare decisions. The common law principle of “**mature minors**” recognizes that capacity to consent is maturity and reasoning-ability based, as well as incremental and situational. The capacity of each youth must be

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considered in the context of each episode of care. It is the responsibility of the treating healthcare provider to assess capacity.

Capacity refers to the ability to understand information relevant to making a decision about the proposed treatment, including:

- a) the condition for which the specific treatment is proposed;
- b) the nature and purpose of the specific treatment;
- c) the risks and benefits involved in undergoing the specific treatment; and
- d) the risks and benefits involved in not undergoing the specific treatment.

- 4.2.1. When the consent giver has a mental illness, the treating healthcare provider must also consider whether the mental illness affects their capacity. Patients admitted under psychiatric care must have capacity assessment done by a psychiatrist.
- 4.2.2. If a patient's capacity to consent is in doubt, a second medical opinion must be obtained and documented. Refer to Decision making about potentially life-sustaining treatment Policy 850. If the capacity is still in doubt, a psychiatrist must be consulted.
- 4.2.3. Capacity is a spectrum which may vary situationally. The treating healthcare provider must re-assess capacity in each instance of consent. A patient may have capacity to provide informed consent in some situations, but not in others, depending on their ability to reason through the risks and benefits involved in more complex treatment decisions.
- 4.3. **Specific:** Informed consent to treatment is specific as to the particular treatment, the treating healthcare provider, and the context.
 - 4.3.1. In the event that more than one procedure is schedule during the same time (for example, under the same general anesthesia session), each treating healthcare provider must separately obtain consent for the specific treatment they will be providing.
 - 4.3.2. An informed consent discussion with respect to treatment by one provider does not automatically transfer to the same treatment being provided by another provider. Consent givers must be advised of care-provider changes, and must be informed that the IWK is a teaching hospital and that the treating healthcare provider may involve physicians or other healthcare providers-in-training in the provision of care.
 - 4.3.3. Informed consent will no longer be valid where the patient's circumstances or plan of care have changed since consent was obtained. (Refer to Duration of Consent, s. 7).
- 4.4. **Informed:** The consent giver must receive full disclosure of all material and relevant information from the treating healthcare provider. Proper disclosure includes discussing the following, in language that the consent giver can understand:

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- a) the nature, gravity and purpose of the proposed treatment and why the treatment is being recommended;
- b) the intended benefits of the treatment and the likelihood of achieving such benefits;
- c) all material, special, or unusual risks (a material risk can include a grave consequence for which there is low probability or a minor consequence for which there is a high probability);
- d) reasonable alternatives to proposed treatment if any exist;
- e) the possible long-term impact of the treatment;
- f) consequences of refusing the treatment;
- g) where treatment involves an associated cost this should be part of the informed consent; and
- h) any special and unusual risks (those that are not ordinary, common, everyday matters, but are known to occur occasionally).

The general rule is that a physician or treating healthcare provider must disclose all information that a reasonable person in the particular patient's circumstances would want to know before choosing to accept or reject the treatment. Any specific questions posed by the patient or SDM must also be answered and be documented.

5. **REFUSAL OF CONSENT:** The treating healthcare professional must recognize the right of a patient with capacity, or their SDM, to refuse treatment.
 - 5.1. If the patient (including a mature minor) has capacity and refuses to consent to the proposed treatment, that decision cannot be overturned. Even in emergencies, treatment cannot be administered which violates the known expressed wishes of a patient who has capacity to consent. This applies even where refusing treatment may result in death or injury.
 - 5.1.1 In extreme circumstances, if refusal of treatment will expose the patient to serious illness or death, any member of the healthcare team may make a report to the Department of Community Services (for patients under 19 years old) regarding the harmful consequences of the patient's choice under the duty to report in the Children and Family Services Act. Note that mature minors are recognized in Canadian law as having the right to make such decisions, so DCS may decline to intervene.
 - 5.2. The SDM for a patient who lacks capacity can legitimately refuse consent to treatment, but the right to refusal is less broad than it is for patients with capacity making their own decisions. Specifically, the SDM must make decisions: 1) according to the prior expressed wishes of the patient; 2) according to the patient's values and beliefs; 3) acting in the best interests of the patient.
 - 5.2.1. In cases where the refusal of treatment by an SDM exposes the patient to risk of serious illness or death, which in the opinion of the treating healthcare provider could otherwise be prevented, there is a duty to notify the Department of Community Services of "a child in need of protective

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services". The *Children and Family Services Act* recognizes that minors need protective services in (but not limited to) the following situations:

"22(2)(e) a child requires medical treatment to cure, prevent or alleviate physical harm or suffering, and the child's parent or guardian does not provide, or refuses or is unavailable or is unable to consent to, the treatment; **or**

"22(2)(h) the child suffers from a mental, emotional or developmental condition that, if not remedied, could seriously impair the child's development and the child's parent or guardian does not provide, refuses or is unavailable or unable to consent to, or fails to cooperate with the provision of, services or treatment to remedy or alleviate the condition"

- 5.3. The duty to report under the *Children and Family Services Act* applies to "every person who performs professional or official duties with respect to a child, including a) a health care professional, including physician, nurse, dentist, pharmacist or psychologist; b) [...] a social worker, [or] family counsellor; who, in the course of that person's professional or official duties, has reasonable grounds to suspect that a child" is in need of protective services as defined above. The treating healthcare provider may report directly to Department of Community Services themselves, or can notify an IWK social worker who will then report to the agency.
- 5.4. The consent giver may partially refuse components of a proposed treatment, but consent to other components of the treatment. The scope of the consent must be clearly documented by the treating healthcare provider.
- 5.5. An consultation to the IWK Clinical Ethics Committee can be sought if there is disagreement with the consent giver's wishes and the treating healthcare provider.

6. **WITHDRAWAL OF CONSENT:** Consent to treatment may be withdrawn by the patient with capacity or the SDM at any time. This withdrawal of consent can be reported to the treating healthcare provider or to any other member of the healthcare team, who will then notify the treating healthcare provider. Withdrawal of consent must be documented.

7. **DURATION OF CONSENT:** Consent to treatment is valid until it is withdrawn, the treatment is completed, or circumstances change which require further discussion with the consent giver (for example, the patient's condition has changed, or a new treatment is now available, or there have been technological changes in the procedure/treatment). Documentation of a new informed consent process must be made by the treating healthcare provider.

8. **DOCUMENTATION OF CONSENT:** Depending on the circumstances, documentation of consent may take the form of a simple note in the chart, a detailed note documenting the specifics of a discussion, and/or a formal consent form. Relevant factors include: level of risk of the treatment, invasiveness of a procedure, unusual risks, particular concerns

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raised by the consent giver, anxiety, tension, or potential conflict around the discussion. Remember, a signed consent form is not a replacement for a valid informed consent discussion; it is a tool to assist documentation of the informed consent process.

- 8.1. Reliance on implied consent should be avoided if possible, excluding general, routine ambulatory care.
- 8.2. Where only verbal consent is obtained, the treating healthcare provider must document in the health record the extent of the consent discussion and the fact of the patient's verbal consent or refusal of consent.
- 8.3. When the *Consent to Treatment and Investigative Procedures* form or a purpose- or program-specific consent form is used, the form must document the material considerations relevant to the consent decision, including risks of treatment. Both the treating healthcare provider obtaining the consent and the consent giver must sign the consent form.

9. **EMERGENCY TREATMENT:** The only time a patient can be treated without consent is in an emergency situation where:

- the patient is unable to consent and no SDM is available within the required timeframe needed to treat; and
 - the medical treatment is necessary to preserve the life or health of the patient; and
 - the delay involved in obtaining consent may pose a significant risk to the patient; and
 - there is no information available that makes it clear that the patient would not want the required treatment.
- 9.1. In these circumstances, the treating healthcare provider must:
 - proceed with the necessary treatment;
 - document the circumstances in the patient record, including the medical condition of the patient as well as any attempts made to contact SDM(s); and
 - if possible, obtain consent from the patient or SDM for yet to be provided treatment as soon as possible, and if not possible, discuss the situation with the patient/SDM as soon as possible.
 - 9.2. Members of the healthcare team must make a reasonable attempt to check for indications of the patient's wishes in the patient's health record. If the treating healthcare provider has prior knowledge of the patient's documented wishes or orally expressed wishes, they must be honoured.

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10. OBTAINING AND DOCUMENTING CONSENT IN SPECIAL CIRCUMSTANCES

- 10.1. **Language interpretation:** When an interpreter is required the IWK makes every effort to ensure an appropriate interpreter is obtained. The IWK contracts health interpretation services, for both face to face or telephone/remote interpretation services. Refer to the Interpretation of Languages Policy 1137 and visit Language Service on Pulse for information on booking an IWK contracted interpreter. When an Interpreter has been involved in the consent to treatment process they (in addition to the treating healthcare provider and the consent giver) must sign the **Consent To Treatment and Investigative Procedure form** as an additional witness. Having the Interpreter's name for clarification, should an issue arise out of the consent process, is important. If remote (telephone or screen based) interpretation is used, note the name and ID# of the interpreter.
- 10.2. **Phone consent:** Ideally, informed consent discussion will occur in person between the treating healthcare provider and the consent giver. Refer to IWK's Telepractice Policy 1802, in the case where consent must be provided by an SDM who is not available in person, all attempts must be made to contact the appropriate SDM via telephone to obtain consent. If the attempt to contact the SDM is unsuccessful, and the situation is not an emergency, treatment should not proceed until consent can be obtained from the appropriate SDM. Consent obtained over the telephone is subject to all the same requirements for valid informed consent outlined previously; in addition, consent must be appropriately documented, either in the patient chart (progress notes) or on the reverse of the applicable consent form by the treating healthcare provider, and must include:
- a) the reason why the patient was unable to consent;
 - b) the name of the treating healthcare provider placing the call;
 - c) the time and date of the call;
 - d) the number called, name of the person telephoned and his/her relationship with the patient (i.e. confirm that person is the appropriate SDM);
 - e) an outline of the nature, benefits and risks of the procedure; and
 - f) the name and position of the witness to the call.

Sometimes, the SDM will have provided consent in writing in advance of the treatment day, and another individual may be accompanying the patient to the appointment/admission. These prior consent discussions and signed consent forms can be relied upon for the current appointment/admission so long as they apply to the specific appointment/admission or time period, and the informed consent process/discussion already took place with the SDM (refer to s. 7, Duration of Consent for guidance).

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10.3. **Consent via telehealth:** Refer to IWK's Telepractice Policy (1802) for guidance on how to obtain consent for use of Telehealth for a healthcare consultation. All principles of informed consent in this policy must be adhered to in any discussion of consent to treatment. Consent to treatment must be documented on the *Consent to Treatment and Investigative Procedures* form and must be witnessed according to the same procedure outlined in Telephone consent, Section 10.2, above.

10.4. **A PERSON WITH low literacy OR WHO IS BLIND OR partially sighted OR who requires the USE of AN Assistive Device to help in understanding the exact wording of the consent form**

If the Consent Giver has low literacy, then in addition to the appropriate consent discussion, the exact wording of the consent form should be read to the consent giver. If the Consent Giver cannot write, they may sign with an "X". Consent documented in this manner must be witnessed by a second healthcare provider, according to the same principles outlined in Telephone consent, Section 10.2, above.

If the Consent Giver is a person who is blind, or is partially sighted and does not have an assistive device to help with their reading, then in addition to the appropriate consent discussion, the exact wording of the consent form should be read to the consent giver. In this case, the person witnessing the discussion must provide (i) their signature in the witness portion of the form, (ii) indicate the Consent Giver's name where the Consent Giver would normally sign the consent form, (iii) indicate that the Consent Giver is a person who is blind, or is partially sighted, (iv) indicate the Consent Giver's relationship to the patient (if not the patient). **The person obtaining consent from a person who is blind, or is partially sighted or SDM cannot be the Witness.**

11. CONSENT FOR SPECIFIC TYPES OF TREATMENT

11.1. **Anesthesia Consent:** Consent for anesthesia is not usually included in the discussion or documentation of consent for an invasive procedure, or documented on the *Consent to Treatment and Investigative Procedures* form by the treating healthcare provider performing that procedure. Consent for anesthesia must be obtained by the attending anesthesiologist (or an appropriate delegate) and recorded on the appropriate section of the anesthetic record, or in circumstances where anesthesia itself is the primary procedure, on a separate *Consent to Treatment and Investigative Procedures* form.

11.2. **Transfusion of Blood Component and Blood Products:** The administration of blood components/blood products is considered a treatment which must be consented to and documented, either as part of the treating healthcare provider's process for obtaining procedural consent, or as a stand-alone treatment. The

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general principles of informed consent and refusal apply, including the provisions about SDMs consenting or refusing on behalf of minors. Please refer to the Policy Administration of Blood Components and Plasma Protein Products for specific considerations (Policy# 625).

- 11.3. **Consent for organ or tissue donation:** Consent for organ or tissue donation is obtained by the Organ Donor Coordinator from the Critical Care Organ program or the Provincial Organ and Tissue Donation Program. Organ donation may proceed only if the requirements of the Nova Scotia *Human Tissue Gift Act* and policies of the Provincial Organ and Tissue Donation Program are met. (See Organ & Tissue Donation Policy #1512). The principles of informed consent outlined in this policy apply.

12. IWK resources are available for treating healthcare providers who need assistance with consent for treatment related matter, see Appendix C.

REFERENCES

Nova Scotia *Hospitals Act* <https://nslegislature.ca/sites/default/files/legc/statutes/hospitals.pdf>

Nova Scotia *Personal Directives Act*

<https://nslegislature.ca/sites/default/files/legc/statutes/persdir.htm>

Nova Scotia *Human Tissue Gift Act*

<https://nslegislature.ca/sites/default/files/legc/statutes/humants.htm>

Nova Scotia *Children and Family Services Act*

<https://nslegislature.ca/sites/default/files/legc/statutes/children%20and%20family%20services.pdf>

College of Physicians & Surgeons of Nova Scotia. Professional Standard & Guidelines Regarding Informed Patient Consent to Treatment. <https://cpsns.ns.ca/wp-content/uploads/2017/10/Informed-Patient-Consent-to-Treatment.pdf>

Canadian Medical Protective Association. Consent: A Guide for Canadian Physicians.

<https://www.cmpa-acpm.ca/en/advice-publications/handbooks/consent-a-guide-for-canadian-physicians>

RELATED DOCUMENTS

Forms

General Patient Care Consent

General Consent for Newborn Care

Consent to Treatment and Investigative Procedures

Refusal of Blood Components/Blood Products

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Appendix “A” – Definitions

- a) **Capacity** - the ability of the patient/SDM to understand the information relevant to making the treatment decision, including; the diagnosis, the nature and purpose of the recommended treatment, the risks and benefits of undergoing the treatment or not undergoing the treatment, and the ability to reason his/her way to a decision.
- b) **Consent Giver** - the **patient**, if he/she has the Capacity to consent on his/her own behalf (this includes Mature Minors). If the patient does **not** have the Capacity to consent on his/her own behalf, then the Consent Giver will be the **SDM (“SDM”)**, as defined below.
- c) **Mature Minor** - a minor (person under 19 years of age) who has the capacity to consent to treatment on their own behalf. In Nova Scotia, there is no ‘age’ of consent – rather the relevant consideration is one’s capacity.
- d) **Personal Directive** - a written legal document created by an individual (the “maker”) setting out instructions or express wishes about their future personal care decisions (including healthcare and medical decisions), and/or appoint a “delegate” to make such personal care decisions on their behalf. In order to be considered a valid legal document, a Personal Directive must be in **writing**, and must be **dated, signed, and witnessed**. A Personal Directive becomes effective whenever the maker lacks Capacity to make a personal care decision. Personal Directives are written documents, defined and legislated under the Nova Scotia *Personal Directives Act*.
- e) **Substitute Decision Maker (or “SDM”)** - the person who will give consent on behalf of the patient if the patient does not have the Capacity to consent. Refer to Policy section 3.3 for more detail regarding selection of SDM.
- f) **Treatment** - any examination, procedure, service medical or health care treatment that is done for a therapeutic, preventative, palliative, diagnostic or other health-related purpose, and includes a course of health care or a care plan. Treatment includes but is not limited to surgeries and procedures, administration of drugs or other interventions, and indirectly to physical interactions (ex. physical contact, venipuncture, or exposure to radiation) or verbal interactions (ex. emotional support or psychological interventions).
- g) **Treating Health Professional** - a person who is recommending, directing and responsible for the patient’s Treatment. This is often the physician, nurse practitioner, registered nurse, or other allied health professional providing care to an IWK patient. The Treating Health Professional is responsible for obtaining consent from the patient/SDM are also required to adhere to their profession’s guidelines on informed consent for treatment.

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Appendix C - IWK Resources

1. IWK Clinical Ethics Committee
2. Interprofessional Practice Council
3. Nursing and Clinical Supports Manager
4. Diversity and Inclusion Coordinator

District Health Authority/IWK Policies Being Replaced

(Please List)

Version History

(To Be Completed by the Policy Office)

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)

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