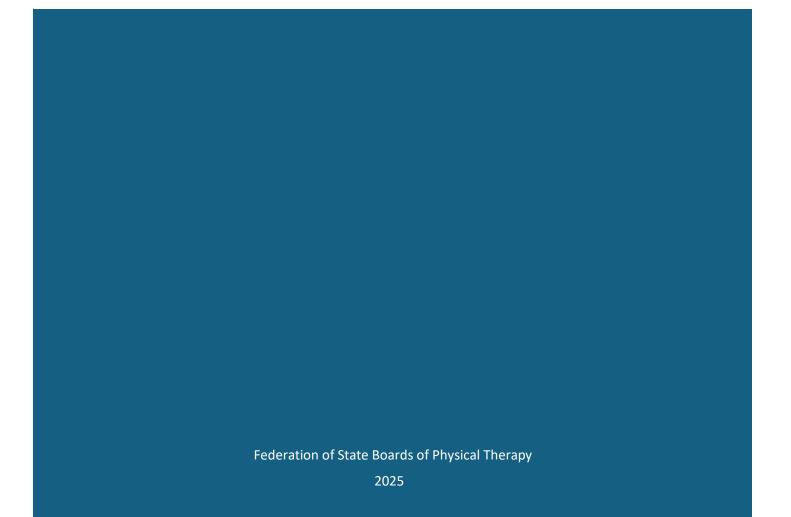
Informed Consent Guide for Physical Therapy

A cornerstone of public protection and ethical practice



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Contents

SECTION 1: INTRODUCTION, INFORMED CONSENT DEFINITION AND GUIDELINES	.2
INTRODUCTION	.2
DEFINITION	.2
Why is it important?	.2
What is the process of obtaining informed consent?	3
SECTION 2: PRINCIPLES OF CONSENT	.4
Types of Informed Consent	.4
Timing & Responsibility for Obtaining Consent	.4
SECTION 3: CAPACITY TO GIVE CONSENT	6
SECTION 4: INFORMATION SHARING AND EXCHANGE	.7
SECTION 5: DOCUMENTATION OF INFORMED CONSENT	9

Informed Consent Guide for Physical Therapy

SECTION 1: INTRODUCTION, INFORMED CONSENT DEFINITION AND GUIDELINES

INTRODUCTION

Informed consent serves as a fundamental element in safeguarding the public. This document aims to provide member boards with a comprehensive overview of the current best practices regarding informed consent and addresses frequently asked questions. Guidance and commentary for incorporating informed consent into jurisdictional physical therapy practice acts can also be found in the Federation of State Boards of Physical Therapy's (FSBPT) Model Practice Act.

DEFINITION

Informed Consent means the educated decision made by a patient/client, or legally authorized representative, to either pursue or refuse physical therapy in whole or in part following the reasonable disclosure of information including the nature, benefits, risks, alternatives of care, the risks of refusal and the identity and qualifications of the provider(s). Prior to beginning physical therapy services and throughout the episode of care, the patient/client must be given reasonable opportunity to ask questions, have them answered, and resolve concerns. Informed consent may be withdrawn or modified by the patient/client at any time.

Why is it important?

- **Public Safety**: Ensures the patient/client are aware of risks, minimizing harm and promoting better outcomes
- **Patient/Client Autonomy**: Respects the patient/client's right to make decisions about their own body and health
- Shared Decision-Making:
 - o Helps the patient/client feel more confident and involved in their treatment plan
 - Encourages collaboration between the patient/client and provider, fostering trust
- Sets Professional Expectations and Boundaries:
 - Clearly defines the treatment process while setting boundaries for the patient/clientprovider relationship
 - This ensures both parties understand their roles and responsibilities, fostering effective communication for future interactions

Informed consent is not just a legal requirement; it's a cornerstone of ethical practice. It ensures the patient/client is empowered, respected, and actively involved in their healthcare journey. Failing to

obtain informed consent can lead to serious legal consequences for healthcare providers and institutions. It can further result in damage to the patient/client-provider relationship, including loss of trust in the provider or the profession.

What is the process of obtaining informed consent?

- **Explain** the planned intervention in lay terms and identify possible providers of the intervention
- **Disclose** the <u>risks</u> associated with the intervention or the lack of intervention
- **Outline** the expected <u>benefits</u> of the intervention
- Present any reasonable <u>alternatives</u> to the intervention and their risks
- **Review** the anticipated time frames and costs of the intervention
- **Provide** the opportunity to ask questions and/or express concerns
- **Reveal** the use of technology including artificial intelligence (AI) when collecting medical history, recording treatment discussions, or documenting of informed consent
- Educate the patient/client of their right to modify or withdraw consent at any time
- **Document** the informed consent process (Section 5)

Key Takeaway

Informed consent is not just a legal requirement, it's a cornerstone of ethical practice. To protect the public and avoid legal or ethical consequences, physical therapy providers must ensure that they:

- Communicate all necessary information clearly
- Respect the patient/client's decision to modify or withdraw consent at any time
- Document the informed consent process

SECTION 2: PRINCIPLES OF CONSENT

Types of Informed Consent

There are two types of consent:

- **Explicit (written or verbal)** Patient/Client clearly states their decision by providing it in writing or speaking it aloud.
 - Written consent is recommended when:
 - performing invasive procedures
 - discussing the significant risks and/or common side effects likely to influence the patient/client's decision-making process
 - Verbal consent may be acceptable for more routine and low risk physical therapy care, provided it is documented adequately
- Implied Patient/Client's actions or behaviors suggest that they agree to something; this may include body language such as head nodding or actively following provider instructions (e.g. patient/client holds out an arm when provider asks to assess range of motion or blood pressure; patient/client performs an exercise that the provider has just demonstrated without voicing concerns). There may be circumstances where implied consent is sufficient as patient/client-provider interactions may not rise to the level of explicit consent.

It is not the intent of this document to define each possible situation. Member boards may refer licensees to their jurisdiction's practice act to identify requirements regarding specific situations where written consent is required (e.g., dry needling, pelvic floor therapy).

Timing & Responsibility for Obtaining Consent

The informed consent process is <u>ongoing</u> throughout physical therapy services, not just a one-time event. Jurisdictions may have regulations as to how often it must be obtained. It is important to note that informed consent normally authorizes a specific provider to carry out the services. The patient/client always has a right to consent or refuse care, including re-assignment of services to another provider.

Generally, it is recommended that informed consent be obtained as follows:

• Initial Consent: prior to beginning physical therapy services (assessment and/or treatment)

Responsibility: Physical Therapist (PT) is responsible for obtaining the initial informed consent; <u>this responsibility cannot be delegated</u> to others.

• **New Consent**: when there is significant change to the patient/client's condition, capacity, the plan of care, or expected outcomes or risks; new information becomes available; or the patient/client voices concerns or a desire to change the plan

Responsibility: As with initial consent, the PT is responsible for obtaining the initial informed consent; <u>this responsibility cannot be delegated</u> to others.

• **Reaffirmation**: informally reaffirmed throughout the duration of the treatment; no change to the plan of care

Responsibility: The PT or physical therapist assistant (PTA) working with the patient/client for ongoing physical therapy should continue the informed consent process within the parameters of their license.

Gaining consent may not be possible in some situations, including:

- Patient/client refuses the information
- Patient/client's mental or emotional state does not allow them to make a rational decision
- Emergency situations where delays in care may cause injury

In these situations, providers should document the situation (e.g., attempts made by provider, patient/client refusal, nature of the emergency), but may proceed with necessary interventions that align with the patient/client's best interests.

Key Takeaway

The informed consent process is continuous during physical therapy services, rather than a one-time event. It is essential to understand that a patient/client signing a form (without prior discussion with the provider) or simply attending a physical therapy appointment does not equate to informed consent.

SECTION 3: CAPACITY TO GIVE CONSENT

The patient/client must have the capacity to consent to the treatment plan outlined by the PT. Capacity encompasses a patient/client's ability to comprehend, weigh, reason and apply the information disclosed regarding the proposed physical therapy intervention and communicate about it clearly and in their own words. Capacity to consent is generally defined in terms of four dimensions or criteria:

- **Understanding:** the patient/client's ability to comprehend the information, including the risks and benefits of the proposed treatment and/or alternatives
- Appreciation: the patient/client's ability to apply the relevant information to their own situation
- **Reasoning:** the patient/client's analytical thinking and rational consideration of the options communicated by the provider
- Expression of choice: the ability to communicate an authentic decision to accept, maintain, modify, withdraw or refuse physical therapy services, or to freely appoint a proxy who will act in the patient/client's best interest

Adults are presumed to have capacity until proven otherwise. If an adult is found to lack capacity, consent must be obtained from a patient/client's legally authorized representative acting in their best interest. The options available to assist with decision making on behalf of a patient/client who lacks capacity may include a personal directive that designates a health care agent empowered with a range of options, including full legal authority, supported decision-making, and a trust or guardianship.

A patient/client under the age of consent (typically eighteen years of age in most jurisdictions) is generally considered to lack capacity. If a patient/client is under the age of consent, it is presumed that consent must be obtained from the legally authorized representative.

PTs do not make legal determinations of a patient/client's competence, which describes one's ability to participate in legal proceedings or transactions; therefore, within physical therapy, the correct term to use is <u>capacity</u>. A patient/client's capacity to make healthcare decisions is not synonymous with their level of competence.

Key Takeaway

- A patient/client must have the capacity to understand and communicate about their treatment decisions
- Adults are presumed capable unless proven otherwise, while minors typically require consent from a guardian.
- Laws related to capacity and informed consent will vary by jurisdiction and may be situation-dependent.

SECTION 4: INFORMATION SHARING AND EXCHANGE

Critical Components and Considerations

The informed consent process should help to manage patient/client expectations of the treatment while building a trust relationship. Effective communication between a provider and a patient/client enhances this process and reduces the likelihood of ethical or legal consequences.

Tips for Better Communication

- **Tailor Communication**: Adapt communication style to fit the patient/client's preferences and comprehension level, considering factors like age, cultural background, and health literacy. This may include the need for a translator and/or designated patient/client representative.
- Use Clear Language: Avoid medical jargon and use simple, straightforward language when explaining the treatment plan.
- **Create a Comfortable Environment**: Foster an atmosphere where the patient/client feels safe and comfortable discussing their concerns without feeling rushed.
- **Individual Considerations:** Respect personal boundaries and individual sensitivities related to gender of provider, physical touch, conversation, and space.
- **Teach-Back Method**: Ask the patient/client to explain the treatment plan in their own words to confirm their understanding.
- **Provide Written Materials or Visual Aids**: Offer brochures or handouts that summarize key points, making it easier for the patient/client to review information later. Use diagrams, charts, or videos to illustrate complex concepts and make them more accessible. Document the materials provided in the medical record.
- **Involve Family Members**: Encourage the patient/client to bring family or friends to appointments to support their understanding and decision-making. Allow time for family discussion between appointments to review the information.
- Identify the Care Team: Notify the patient/client of staff qualifications, including the use of PTAs, students and technicians in care delivery. Review the patient/client's right to choose their provider and be seen by a PT upon request.
- **Check-Ins**: Regularly revisit the treatment plan and address any new questions or concerns.
- **Encourage Questions**: Invite patient/client to ask questions and clarify any uncertainties they may have about their treatment. The provider should demonstrate empathy for patient/client concerns and questions.

Respecting Boundaries and Information Sharing

- If the patient/client declines to receive the information, the provider should not force further discussion, and refusal should be documented accordingly.
- The patient/client must provide explicit permission for others to participate in the informed consent discussion. This includes the use of technology including AI recording devices or programs.

- Information should not be withheld from the patient/client even if:
 - \circ $\;$ the provider believes the patient/client might decline care
 - o requested by a relative or caregiver

Key Takeaway

Jurisdictional boards may consider fostering education and programs that promote effective communication styles between the patient/client and provider, enhancing the informed consent process.

SECTION 5: DOCUMENTATION OF INFORMED CONSENT

Documentation of informed consent provides evidence that a patient/client or their representative was adequately educated about a course of treatment, understood the risks, benefits and alternatives, and voluntarily agreed to or declined treatment. Informed consent generally does not need to be in written form to be valid. However, written consent is recommended when risks of treatment are serious or common. When consent is provided in written format, a consent form does not serve as a substitute for an informed consent conversation between the provider and the patient/client or representative; it is advisable for the provider to document such a conversation occurred.

Jurisdiction boards may consider the following when reviewing documentation of informed consent:

- When informed consent is obtained verbally, documentation of the consent conversation may include relevant elements such as:
 - Patient/client capacity
 - How and when consent was provided
 - Specific questions or topics covered
 - Specific risk factors based on medical history, medication, etc.
 - Reference to any provided educational handouts or resources
- While consent does not typically "expire," it should be documented again if:
 - A significant amount of time has passed since the last consent
 - Patient/client circumstances change
 - New information about the proposed intervention is available
 - Changes are made to the plan of care
- Patient/client refusals should be documented in the physical therapy record, indicating the patient/client:
 - o was informed of the risks of declining treatment
 - o understood those risks
 - o voluntarily declined the specific treatment
 - o signed a refusal of care document (optional)
- If the informed consent conversation is recorded using technology including an AI device or program, the patient/client must provide consent to be recorded before the conversation takes place.

Key Takeaway

Proper documentation of informed consent serves to protect the public and as a legal safeguard for both the patient/client and licensee, confirming that the informed consent process was conducted ethically and transparently.

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