# AAH RSPP GUIDANCE
# Substitute Decision Makers/Legally Authorized Representatives (LAR) in Human Subject Research Enrolling Adult Subjects

PURPOSE

Adult patients are presumed to have decision-making capacity and are the appropriate decision maker for their own medical care. For research this tenet also holds true. It is assumed that the adult prospective subject has the decisional capacity to make informed decisions on research participation for themself, unless otherwise confirmed through a decisional capacity assessment.

Federal research regulations state that when decisional incapacity renders an adult potential research subject unable to provide informed consent for participation in a research study, the investigator must obtain written informed consent from a "legally authorized representative (LAR)" prior to enrolling the potential subject into the research study. Under federal regulations, a legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [45 CFR 46.102(c)]. The issue as to who can be an LAR is determined by the laws of the jurisdiction in which the research is conducted.

Some states have statutes, regulations or common law that specifically address consent by someone other than the subject for participation in the research. Wisconsin and Illinois state laws are, for the most part, silent on the issue of use of LAR or a *substitute decision maker* (SDM) in human subject research (HSR), so laws on who is authorized to give consent on behalf of another person to specific medical procedures or generally to medical treatment are applicable to the research setting.

This guidance document outlines the AAH RSPP ('RSPP') position/policy on the use of a substitute decision maker in human subject research. Guidance and processes provided in the AAH system policy for the use of substitute decision makers in clinical care (Policy #69294: *AAH Patient Decision-Making Capacity and Substitute Decision-Making)* are used to guide RSPP policy for local human subject research participation by adult individuals who lack decisional capacity.

It should be remembered that it is the IRB of record's responsibility to determine whether it is appropriate for, and approve the use of, a substitute decision maker to make decisions on behalf of an adult individual who lacks decision-making capacity for research purposes. In research studies overseen by the AAH IRB, it is the AAH IRB that makes this decision. The AAH IRB uses this guidance document to direct their decision making in this matter. For studies ceded to an external IRB, the reviewing IRB would be the body to make the decision on the use of LAR/SDM in the research study. However, many external IRBs seek direction from the relying institution on whether the use of a LAR/SDM in a given study is acceptable to the

institution and under state law. No matter which IRB makes the decision, the ethical principles of Justice, Beneficence and Respect for Persons, as well applicable state laws, must be considered.

Note that this guidance does not govern enrollment of children into research studies, nor "emergency research" (21 C.F.R. § 50.24). See other RSPP guidance documents on these topics.

Definitions of *Italicized words* can be found in the AAH RSPP Glossary located in the RSPP website.

GUIDANCE

**What is the position of AAH on the use of a LAR/SDM in HSR?**

Advocate Aurora Health (AAH) has not adopted policy or position on the use of LAR/SDM in human subject research.

AAH does have a clinical system policy 69294: *AAH Patient Decision-Making Capacity and Substitute Decision-Making* that directs team members on decision-making capacity of patients and possible use of SDM in the clinical setting. This clinical policy states that the adult patient is presumed to have appropriate decision-making capacity and is the appropriate decision maker for health care decisions unless:

1) responsible health care professional(s) (WI)/attending physician (IL) determines and documents that the person lacks the capacity to make their own health care decisions;

**OR**

2) The decisional patient has delegated their health care decision-making to someone else (via advance directive).

When it has been determined that an adult patient lacks decision making capacity in the clinical setting this determination may be found in the patient's electronic health record.

**What is the position of the RSPP on the use of a LAR/SDM in HSR for adult individuals?**

It is the position of the AAH RSPP that the decision to participate in human subject research should be made by an adult individual who has the decisional capacity to make informed decisions about research participation for him/herself, and that a substitute decision maker should make the decision about an individual's participation in research ONLY IF

1. there is a clear evidence/decision that the individual lacks decision-making capacity;

**OR**

2. the decisional patient specifically delegates their research decision-making to someone else in an advance directive.

If the IRB has determined that surrogate consenting may be used in a research study, the RSPP's position is that the LAR/SDM should make decisions that are: 1) in alignment with the subject's known wishes, and 2) always made in the subject's best interest.

**What does state law say about the use of a substitute decision maker in HSR?**
In **Wisconsin,** state law addresses the issue of who may provide consent for research participation on behalf of an adult determined to lack decisional incapacity only: (a) when experimental treatment is aimed at individuals being treated for mental illness, developmental disabilities, alcoholism or drug dependency (as described further below); and (b) in chapter 54 of the Wisconsin Statutes ("Guardianships and Conservatorships"). In all other areas of HSR, Wisconsin law is silent on the use of LAR/SDM .

Wisconsin statutes (Wis. Stat. § 51.61(l)(j) and regulations (Wis. Adm. Code DHS § 94.14)) expressly prohibit obtaining informed consent from a guardian, alone, for research involving incompetent subjects who are being treated for mental illness, developmental disabilities, alcoholism or drug dependency. And Wisconsin statues (Wis. Stat. § 155.20(3)) also preclude a health care agent from consenting to the principal's participation in experimental mental health research. In light of these restrictions, in the state of **Wisconsin**, **adults who lack decisional capacity may not be enrolled into research studies that involve treatment for mental health, developmental disabilities or alcohol or drug abuse.**

In **Illinois,** state law is silent on the use of substitute decision makers/legally authorized representatives in human subject research.

**Who makes the decisional incapacity determination for research participation?**
RSPP policy on who may make the decisional capacity determination for research consent uses the guidance/processes outlined in the AAH policy # 69294: *Decision-making Capacity and Substitute Decision-Making* in the clinical care context (see below or in the system policy). Pursuant to this policy, applicable provisions of the law of the state in which the patient obtains treatment govern who may make the decisional incapacity determination and who may serve as the substitute decision-maker for clinical care. For research, the laws of the state where the individual will be enrolled into the research study will be used in determining who can make the decisional incapacity determination and who may serve as LAR.

A decisional incapacity determination of an adult person will cover both clinical and research settings. This means that if an adult individual is determined to lack decision making capacity for clinical decisions, the person is also deemed to lack decisional capacity for research decisions. At no time may an individual be determined to lack decision making capacity for research decisions yet be considered decisional in the clinical setting.

The determination of decisional incapacity – both in the clinical and research setting – are to be documented in the patient's electronic medical record.

The following information can be found in more detail in system policy 69294.

A. In the state of **Wisconsin**, an assessment of incapacity for purposes of activating a Wisconsin Power of Attorney for Health Care (POAHC) requires that two physicians or a physician and an APRN, PA or licensed psychologist who have personally examined the patient, determine and document that the patient lacks decision making capacity. The individual named on the advance directive as "agent" is the substitute decision-maker for the adult patient.

   If a patient in Wisconsin does not have a Power of Attorney for Healthcare (POAHC), AAH system policy allows the responsible health care professional (i.e., physician, APRN, PA or licensed psychologist) to determine and document their assessment of the patient's lack of decision-making capacity and identify a substitute decisionmaker for the patient.

   It is the position of the RSPP that in the research context, the **health care professionals making the incapacity determination should not be part of the research team**.

B. In the state of **Illinois**, in the clinical setting, the Illinois Health Care Surrogate Act (IHCSA) allows for the attending physician to make the determination of incapacity and to identify the appropriate substitute decision maker if the adult patient has no applicable advance directive.

   Given that the incapacity decision in Illinois is made only by one individual (i.e. the attending physician), it is the position of the RSPP that when the incapacity decision is to be used to allow a SDM/LAR to make decisions on research participation, **the attending physician should not be part of the research team.** If the attending physician is part of the research team, a second physician must make a concurring decision on the decisional incapacity of the prospective adult subject. This concurring decision must take place BEFORE the adult subject is enrolled into the research study. The **concurring physician** may **NOT** be part of the research team.

   **NOTE** in Illinois, the attending and concurring physician's decisions on the incapacity of an adult subject participating in human subject research, as well as the determination of who may act as the subject's substitute decision maker, must be documented on the ***Illinois Health Care Surrogate Act Certification Concerning Research*** form found in the IRBNet library. This certificate must be completed and attached to the IRB approved research informed consent document uploaded into EPIC (or included in the subject's research record if research informed consent is waived by the IRB of record). [See the Certificate for further instruction.]

**Per AAH RSPP policy, who can serve as LAR/SDM for research?**

It is the position of the RSPP that the substitute decision maker/LAR for research follow the guidelines of who my serve as the substitute decision maker/LAR in the clinical setting (per clinical system policy #69294).

The following information can be found in more detail in system policy #69294.

A. In **Wisconsin**, the appropriate SDM is identified in the following order:
    1) Health care agent identified in the patient's POAHC;
    2) Legal guardian of the person, who, per court order appointing them guardian, has authority to enroll the patient in research (Note: copy of court order should be attached to informed consent document);
    3) Other individuals who know the patient's likely treatment preferences and can represent the patient's values and goals, and promote the patient's best interests.

B. In **Illinois,** a substitute decision-maker is identified by the attending physician pursuant to the Illinois Health Care Surrogate Act, once the patient is determined to lack decision-making capacity.

    If the incapacitated patient does not have an agent designated under the Powers of Attorney for Health Care (POAHC) Law, medical treatment decisions may be made by individuals in the following order of priority:
    1) Legal guardian of the person;
    2) Spouse or Civil Union partner (as defined in IL law);
    3) Adult son or daughter;
    4) Parent of the patient;
    5) Adult brother or sister;
    6) Adult grandchild;
    7) Close friend (a Close Friend Affidavit must be completed);
    8) Legal Guardian of the patient's estate.

    **NOTE:** a designated Health Care Agent or Legal Guardian of the person for the patient determined to lack decisional capacity takes precedence in the hierarchy of who can serve as SDM.

    If there are more than two individuals in the relevant category, a majority of available individuals within that category provides the required consent. If majority consensus is not reached, guardianship is considered.

    SDM requirements of the identified individual(s) include:
    1) Must be at least 18 years old;
    2) Possess Decision-Making Capacity;
    3) Be available upon reasonable inquiry; AND
    4) Be willing to make medical treatment decisions on behalf of the patient.

In either state, unless noted in a patient's advance directive, the individual who may act as the substitute decision maker is determined by the person(s) making the incapacity determination (that is the clinical practitioner).

**What are some factors to be taken into consideration by the substitute decision maker in making decisions about the incapacitated individual's participation in research?**
The SDM shall make a decision for an adult subject conforming as closely as possible to what the subject would have done or intended under the circumstances, taking into account evidence that includes, but is not limited to, the subject's personal, philosophical, religious and moral beliefs and ethical values relative to the purpose of life, sickness, medical procedures, clinical research, suffering, and death. An unrevoked advance directive, such as a Living Will, Power of Attorney for Health Care, or Declaration for Mental Health Treatment that is no longer valid due to a technical deficiency or is not applicable to the patient's condition may nonetheless be used as evidence of a patient's wishes.

If the adult patient's wishes are unknown and remain unknown after reasonable efforts to discern them, the decision shall be made on the basis of the patient's best interests as determined by the SDM. In determining the patient's best interests, the SDM shall weigh the benefits to the patient of initiation or continuation in the research against the burdens and risks of the research, and shall take into account any other information, including the view of family and friends, that the SDM believes the patient would have considered if able to act for themself.

**What happens if the decisionally incapacitated adult patient disagrees with the SDM's decision about research participation?**
It is the position of the RSPP that, when possible, the decisionally incapacitated adult patient should be asked if they agree with the decision made by the SDM about enrollment into the research study (verbal 'assent'), and the patient's wishes followed. That is, if the decisionally incapacitated adult patient verbally or physically objects to or resists research participation, this pronouncement should be assumed that the patient does not wish to participate in the research study. As such, the subject should be withdrawn from or not included the research study. The subject's objections are an indication that it is not in their best interest to participate in the research study.

Only in the most extreme cases should it ever be considered that the verbal wishes of the decisionally incapacitated adult patient be overridden by the SDM and PI. If the SDM and PI think it best to include the decisionally incapacitated adult patient in the research study when the patient has objected or provided resistance to research participation, it is the recommendation of the RSPP that a Clinical Ethics consultation be obtained before research participation commences/continues. The outcome of the consultation and the subsequent decision on patient participation in the research should be documented in the research record/EPIC.

If the SDM at any time determines that the subject's participation be stopped, this decision must be followed, and the subject withdrawn from the study.

**Does decision-making capacity need to be reassessed?**
Yes. An individual's decision-making capacity may fluctuate over time. While a subject may not be decisional for some research decisions, they may have decisional capacity at other times. Therefore, to respect the subject's autonomy, assessment of decisional capacity of the research subject should be a continuous process.

Per System policy 69294, it is patient's attending physician/clinical team who is ultimately responsible for the ongoing assessment of decision-making capacity of a patient. However, it is the responsibility of all caregivers to be aware of the subject's condition, and bring concerns/issues to the attention of the attending physician.

In the case of research participation this responsibility extends to the research team. The research team must be mindful of the subject's condition and seek out the attending physician's/clinical care team's assessment of whether the patient's/subject's decision-making capacity has returned.

**What happens if the subject regains decision making capacity while a research subject?**
Clinical assessment of the patient's decision-making capacity should be on-going as indicated in system policy #69294. If the patient was deemed to be non-decisional but appears to have regained decision-making capacity at some point during hospitalization or treatment, a new clinical assessment of decisional capacity must be undertaken as noted in the system policy.

The clinical assessment of decision-making capacity also covers research participation for the patient. If decision making capacity of the patient in the clinical setting has returned, this means that decision-making capacity for the patient in the research setting has also returned.

It is incumbent on the PI and the research team, in coordination with the clinical team, to continuously monitor the enrolled subject and seek formal decisional assessments from the clinical care team/attending physician as needed.

The IRB, in their assessment of whether individuals lacking decisional capacity may participate in the research study, may also consider/require time periods at which the subject's decision-making capacity is reassessed by the clinical team. The IRB's decisions must be followed for the enrolled subject.

Any time a patient's decision-making capacity is re-assessed by the clinical team/attending physician it must be documented in the patient's medical record. It is incumbent on the research team to regularly monitor notations of the clinical team/attending physician in EPIC of the patient's decision-making re-assessments.

- In the clinical setting, if the patient regains decision making capacity, the POAHC or substitute decision maker for health care designation is deactivated.
- In the research setting, should it be determined clinically that decision-making capacity of the enrolled subject has been re-established, decision-making authority

shifts from the SDM to the subject. The subject should be asked if he/she wishes to continue in the research study, and formal research consenting of the individual must occur prior to continued participation in the research study.

If decision-making capacity is re-established, and the enrolled subject declines to continue research participation, the individual's decision must be respected, and the subject withdrawn from the research study.

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**What do I need to do to enroll a subject who lacks decision-making capacity into a research study?**

Information must be provided to the AAH IRB/RSPP when the research team wants to enroll subjects who lack decision-making capacity into the research study.

- The PI may request to use substitute decision makers in the **initial** AAH IRB submission application or AAH Request to Rely on an External IRB application (ceded research), OR
- Should the study team encounter a potential subject who lacks decision-making capability once the research study has already been approved by the IRB, a request may be made to enroll such an individual into the research if not already considered by the IRB. Such a request may be made to the AAH IRB/RSPP via the **Change** process.
    - The appropriate Change form must be uploaded into a new IRBNet package and submitted to the AAH RSPP/IRB.
    - The Change form must include the same information that is required in the initial submission/Request to Rely application related to enrollment of this patient population. (The research team should contact the RSPP office for a copy of the questions to include with their Change form.)

A. No matter when requested, if the **AAH IRB is overseeing the research study**, the AAH IRB will review the responses and determine if the use of a SDM/LAR in the study is appropriate per system policy, ethical considerations, and applicable state law.
    - Study teams will receive the decision (a written approval or disapproval letter/memo) from the AAH IRB once made.
        - If the request to use SDM/LAR is approved by the AAH IRB, adult subjects who have been determined to lack decision-making capacity may be enrolled into the research study going forward.
            - The SDM to be used in the research process will be documented in this decision letter. In making this assessment, the AAH IRB will take into consideration the individual(s) designated by the health care provider as the substitute decision maker(s) during the clinical incapacity decision as outlined per system policy (this information will also be requested as part of the IRB application/Change form).
            - The letter/memo will also outline any additional protection measures required by the AAH IRB that were placed on the inclusion of this subject population (see below).

- If the decision is disapproved, adults lacking decisional capacity may not be enrolled into the research study.

- The IRB determination to include subjects lacking decision-making capacity in the research study only needs to be made once for the research study (not for each subject to be enrolled) unless the information provided by the research team changes.

NOTE questions on the AAH Continuing Review form will ask about inclusion of subjects into the research using a SDM/LAR. The IRB will reconsider the inclusion of this patient population into the study at the time of continuing review.

B. If an **external IRB is overseeing the research study**, the RSPP will review the responses provided on the Request to Rely application or the Change in Ceded research form, and issue a memo on the appropriateness of including this patient population into the research study per institutional policy, state laws and RSPP guidance.
   - The RSPP does **NOT** make the determination of whether subjects who lack decision making capacity may be enrolled into the research study or who will serve as the substitute decision maker for the patient. This decision must be made by the reviewing IRB.
   - The RSPP's role in the process is to provide an assessment of institutional policy, state law and RSPP guidance and whether inclusion of this patient population is appropriate in this research study. The RSPP will also provide a recommendation to the reviewing IRB as to who is recommended to be the substitute decision maker per these guidelines.
   - It is the expectation of the RSPP that this assessment be provided to the external IRB/reviewing IRB. The reviewing IRB may use this assessment to make a decision whether AAH adult patients who lack decision-making capacity may be enrolled into the research study.

**Outside of submitting the request to the IRB/RSPP, are there additional steps that must be taken for enrollment of subjects who lack decisional capacity?**

**Yes**. The study team must retain all pertinent information (in the EMR or subject research record) on the enrollment of such subjects, including the appropriately executed research informed consent document, Surrogate Act Certification for such subjects enrolled in Illinois, and other appropriate research documents, etc..

It is recommended as best practice that research teams make/retain notations on the patient's assessment/re-assessment of decision-making capacity in the subject's research record, as well as attempts to obtain the patient's verbal agreement (assent) to participate in the study.

1. **Research informed consent document**

   Whether a study overseen by the AAH IRB or an external IRB the **research informed consent document must include the appropriate signature section for the SDM/LAR**. This section not only includes a signature line for the SDM/LAR but also a checkbox denoting the relationship of this individual to the subject, and a

checkbox to denote whether assent of the prospective adult subject was attempted/obtained. Both the AAH research consent and research authorization templates, as well as the ceded research consent/authorization boilerplates, include a SDM/LAR signature section (all of these documents can be found in the IRBNet Library).

Once the IRB of record has approved the use of a SDM in the research study, the research informed consent document must be revised to include the SDM/LAR signature section. The research team should follow the IRB of record's instructions on revising the research consent/authorization document and the need for IRB approval of this revised document.

2. **Illinois Health Care Surrogate Act Certification Concerning Research**

   If it is determined by the **AAH IRB** or the **external IRB** (ceded research) that it is appropriate to include adult individuals who lack decision-making ability in the research study, and the **research is conducted in the state of Illinois**, the study team must access (from the IRB Net Library) and complete the *Illinois Health Care Surrogate Act Certification Concerning Research* form **for each adult subject lacking decision-making capacity enrolled into the research study**.

   This form will document the attending physician's decision on the prospective subject's decisional status, as well as document who will act as the substitute decision maker.

   IF the attending physician is part of the research team, a second physician ('concurring physician') must also document their agreement that the individual lacks decision-making ability by signing the form. The concurring physician may NOT be part of the research team. [See the Certificate for more information.]

   The completed Illinois Health Care Surrogate Act Certification Concerning Research form documenting the attending/concurring physician's determination that the individual lacks decisional capacity to make research decisions **MUST** be appended to the executed research informed consent/authorization document that is uploaded into the EMR. If research informed consent has been waived by the IRB of record – then the completed form must be retained in the research records.

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**When the AAH IRB is the IRB of record….**

**Under what circumstances would the AAH IRB most likely consider it ethically appropriate to use a SDM/LAR to make decisions about research participation?**
Unless specifically prohibited by state law, the RSPP most likely would consider it ethically appropriate to allow a SDM/LAR to make research decisions when:

- participation of the individual in the research would align with his/her likely preferences under the circumstances;

  **AND**

- the experimental treatment presents the prospect of direct benefit to the individual, (e.g. no other comparable treatment is available or there is genuine uncertainty about the effectiveness of standard care); **OR**
- risks to the prospective adult subject are small in relation to the potential benefit of the research to society.

**What does the AAH IRB consider in their assessment of whether to allow individuals who lack decisional capacity to participate in the research study?**

In addition to the specifics of the study design, the AAH IRB would consider the following in making their decision:

- does the research study prohibit the use of a SDM/LAR;
- is the research study greater than or less than minimal risk for the subject;
- are there comparable treatments available to the subject outside of the research study;
- are there questions about the efficacy of standard treatments;
- could the study be conducted without the inclusion of individuals who lack decision-making ability;
- would the subject experience an increased risk of harm or discomfort compared to routine medical treatment;
- does the research study offer the prospect of direct benefit to the individual, future patients or society in general.

**What additional subject protection measures may the AAH IRB consider/require in their decision?**

The AAH IRB may also take into consideration the following in their assessment:

- who can act as the substitute decision maker(s)/legally authorized representative;
- should the decisionally incapacitated individual be provided the opportunity to formally assent to participate in the research;
- if/when decisional capacity should be re-tested;
- should the PI personally obtain documented informed consent from the substitute decision maker;
- should the consent process be monitored by an independent person deemed appropriate by the IRB;
- should there be a waiting period between the consent discussion/decision and start of the research activities.

**What is the process for AAH IRB review of this request?**

The research team will make a formal request to include this subject population in the AAH IRB application or AAH Change form. The AAH IRB Primary Reviewer member will complete one of two SDM/LAR checklists: Primary Reviewer Checklist for Enrolling Decisionally Incapacitated

Subjects into Therapeutic Research OR Primary Reviewer Checklist for Enrolling Decisionally Incapacitated Subjects into Non-Therapeutic Research.

If the request is reviewed at a convened AAH IRB meeting, the Primary Reviewer will use the checklist to discuss the request with the board. The AAH IRB's decision will be documented in the meeting minutes (the checklist does not need to be retained). The decision will be provided to the PI in writing. Communication with the PI shall include applicable conditions and limitations, as well as the IRB's consideration of who will serve as the SDM/LAR.

If the request is reviewed via expedited review, the checklist will serve to document the IRB member's decision (the checklist will be retained in the IRBNet package). The IRB's decision will be provided to the PI in writing. Communication with the PI shall include applicable conditions and limitations, as well as the IRB member's consideration of who will serve as the SDM/LAR.

**Does the AAH IRB consider the use of a substitute decision maker/legally authorized representative at the time of continuing review?**
Yes. If the study undergoes a Continuing Review with the AAH IRB, and the AAH IRB has approved the inclusion of adult subjects who lack decision-making ability, the IRB will reconsider the use of a SDM/LAR at continuing review. The AAH Continuing Review application asks the PI questions on the study team's enrollment of subjects using the LAR/SDM process.

- Approval of the continuing review application/study by the AAH IRB without modification should be considered by the PI as continued IRB approval of inclusion of adult subjects who lack decision-making ability.
- If the AAH IRB determines that use of a SDM/LAR is no longer appropriate for the study, the PI will be made aware of the AAH IRB's decision in writing via letter/memo uploaded into IRBNet.

As part of the continuing review for the study, the AAH IRB may request copies of executed informed consent documents signed by the SDM/LAR and/or copies of the Illinois Health Care Surrogate Act Certification Concerning Research if the research is conducted in Illinois.

**May studies that enroll adult patients who lack decision making ability undergo quality audit?**
Yes. Risk is elevated with the inclusion of adult patients who lack decision-making ability into research. Therefore, such studies may qualify for quality audit by AARI. Also, if there is suspicion of wrong-doing or reported incidents of noncompliance on the part of the research team when enrolling such individuals into a research study, the AAH IRB, AAH RSPP Director, or AARI leaders may request a quality review of the study team's practices in this regard.

**RESOURCES**

- AAHRPP Accreditation Standards/Elements: I.1.G;II.3.F, II.4.A, II.4.B
- AAH System Policy: 69294
- Code of Federal Regulations: 45 C.F.R. 46.102(c); 21 C.F.R. 50.3(1); 21 C.F.R 50.24
- Wisconsin state law: Wis. Stat. § 51.61(l)(j), § 155.20(3), § 155.01(8); Chapter 54
- Wisconsin Administrative Code: DHS § 94.14
- Illinois state law: Illinois Health Care Surrogate Act