



**Legally Effective but Ethically Inadequate: *Institutional Review Board Policies for Consent from Legally Authorized Representatives***

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**Table 2.**  
**Locations of LAR Provisions by Policy Category**

<b>Policy category</b>	<b>Number of sites<sup>1</sup> (N = 25)</b>
Specific LAR policy	10
Vulnerable-populations policy	5
General informed consent policy	9
Impaired decision-making policy	10

1. At ten of the sites, LAR provisions were found in more than one policy category.

**Table 3.**  
**Sources for or Approaches to Defining “LAR”**

<b>Source or approach</b>	<b>Number of policies (N = 25)</b>
Pre-2018 Common Rule	11
Revised Common Rule	3
Plain language	3
Either version of the Common Rule and plain language	1
No definition	8

**Table 4.**

**Policies about Hierarchies Used to Determine a Surrogate**

<b>The nature of the surrogate-hierarchy policy</b>	<b>Number of policies (N = 25)</b>
The policy explicitly relies on a hierarchy provided by state law for determining a surrogate to make treatment decisions.	14
It is unclear whether the policy concerns the treatment context.	6
The policy does not refer to treatment.	6
The policy notes the research-treatment distinction.	9

**Table 5.**

**Features That Could Compensate for Ethical Deficiencies in Reliance on the LAR**

<b>Feature of the policy</b>	<b>Number of policies (N = 25)</b>
The LAR's capacity is mentioned.	2
The LAR's capacity is required.	0
The subject values and preferences are mentioned.	8
Relational intimacy between the LAR and the subject is required.	4
Continuous involvement of the LAR is mentioned.	3
Continuous involvement is required.	0
There are risk-related enrollment limitations.	17
There are risk-related limits on LAR consent.	0

**Table 6.**  
**Decision-Making Standards in the Policies**

Decision-making standard(s)	Number of policies (N = 25)
Substituted judgment is mentioned.	8
Substituted judgment is required. <sup>1</sup>	6
Substituted judgment is explained. <sup>2</sup>	5
Use of the best interest standard is explicitly permitted.	7
Use of the best interest standard is required.	6
The policy spoke of the basis for a decision without using any terminology for the standard.	8
The policy includes both the substituted judgment and the best interest standards.	7

1 An additional site required substituted judgment without using that terminology.

2 An additional site explained substituted judgment without using that terminology.