

	<b>INVESTIGATOR GUIDANCE: Documenting Informed Consent</b>				
	<b>NUMBER</b>	<b>DATE</b>	<b>Version No.</b>	<b>RESP. AUTHORITY</b>	<b>PAGE</b>
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## 1 PURPOSE

- 1.1. This guidance describes a process that in general is suitable to document consent in writing.
- 1.2. Other procedures may be suitable when approved by the IRB.

## 2 BACKGROUND

- 2.1. "Person providing consent" means:
  - 2.1.1. In the case of a cognitive intact adult, the individual being asked to take part.
  - 2.1.2. In the case of an adult unable to consent, that individual's Legally Authorized Representative (LAR).
  - 2.1.3. In the case of a child, when determined by the IRB:
    - 2.1.3.1. One parent, if the other parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
    - 2.1.3.2. One parent if the IRB has determined permission from one parent is sufficient.

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