**Saint Louis University Institutional Review Board**

**Checklist for Obtaining Consent: 45 CFR 46.406, 21 CFR 50.53**

When a study is designated as a 45 CFR 46.406/21 CFR 50.53 by the SLU IRB, it means that consent signatures of **both parents are** **REQUIRED**, unless the situation meets the following circumstances:

1. Is the 2nd parent deceased? yes  no

If **yes**, **proceed to #6.**

1. Is the 2nd parent unknown? yes  no

If **yes**, **proceed to #6.**

1. Does only 1 parent have legal custody\* of the child? yes  no

If **yes**, **proceed to #6**. \*as determined by a court of competent jurisdiction.

1. Has the 2nd parent been legally\* declared incompetent? yes  no

If **yes**, **proceed to #6**. \*as determined by a court of competent jurisdiction.

1. Is the 2nd parent reasonably available? yes  no

If **yes**, **obtain consent**.

1. If **no**, is the 2nd parent in the military and presently overseas? yes  no

If **yes**, **proceed to #6**.

1. If **no**, is the 2nd parent in a vegetative state/coma or have a condition that makes meaningful consent impossible, such as a high level of sedation? yes  no

If **yes**, **proceed to #6**.

1. If **no**, is the 2nd parent in prison? yes  no

If **yes,** **proceed to #6.**

1. If **no**, is the 2nd parent available by phone and/or fax? yes  no

If **yes**, consent of the 2nd parent is **REQUIRED**. If **no**, **proceed to #6.**

1. Has information about the 2nd parent’s unavailability been recorded in the research record/consent form\*? yes  no

\*In cases where only one parent signature is obtained, documentation is required in the research record. Include a detailed explanation of the missing 2nd signature, and note the source of the information. *Simply indicating that the parent is not available is not acceptable.*