

# CONSENT CHECKLISTS: REGULATORY CRITERIA

For consent documents on studies that fall under convened or expedited IRB review.

## SIGNATURE REQUIREMENTS

<b>DOCUMENTATION OF CONSENT</b>
<b>Applies to research where written consent will be obtained</b>
<input type="checkbox"/> Research participant signs consent: Consent includes signature lines, date, and printed names for the participant and the person obtaining consent
<input type="checkbox"/> Research participant is a minor (child): <ul style="list-style-type: none"> <li>• Parental Permission includes signature lines, date, and printed names for the parent/guardian(s) and the person obtaining consent.</li> <li>• Includes lines to record the printed name of child and the child’s age.</li> <li>• Some types of research require signature from two parents. (Refer to OPRS policy for full description of parental permission/assent process)</li> <li>• Refer to the Assent / Parental Permission / Proxy (LAR) Consent guidance and checklist for signature requirements from children</li> </ul>
<input type="checkbox"/> N/A
<input type="checkbox"/> Research participant is decisionally impaired or lacks the capacity to consent for themselves: Add a signature line, date and printed name for Legally Authorized Representative. (NOTE: refer to OPRS policy for full description of consent process)
<input type="checkbox"/> N/A
<input type="checkbox"/> Witness signature lines, date, and printed name are required on consent in the following situations: <ul style="list-style-type: none"> <li>• Research participant is non-English speaking and a short form consent will be used</li> <li>• Research participant understands English but is either illiterate (cannot read or write), physically unable to talk or write, blind, or with motor difficulties that prevent obtaining signature.</li> </ul> (NOTE: refer to OPRS policy for full description of these consent processes)
<input type="checkbox"/> N/A