

# CONSENT CHECKLISTS: REGULATORY CRITERIA

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

<b>Food and Drug Administration (FDA) Requirements</b>
<b>Include for FDA regulated research only – drugs, medical devices, FDA regulated products</b>
<input type="checkbox"/> Includes a statement noting the possibility that the FDA may inspect the records
<input type="checkbox"/> Includes a statement that a purpose of the study includes an evaluation of the safety of the test article. Note that statements that test articles are safe or statements that the safety has been established in other studies are not appropriate when the purpose of the study includes determination of safety
<input type="checkbox"/> For studies that evaluate the effectiveness of the test article: Includes a statement of that purpose, but should not contain claims of effectiveness <input type="checkbox"/> N/A – study is not evaluating efficacy of an FDA regulated product
<input type="checkbox"/> For research involving an investigational drug, device, biologic, or Humanitarian Use Device (HUD): the consent states the regulatory status of the agent using explanations designed to be understood by the targeted subject population. <input type="checkbox"/> N/A – only approved FDA regulated products will be used in the research, according to their approved indications
<input type="checkbox"/> For FDA regulated clinical trials, subject withdrawal: <ul style="list-style-type: none"> <li>• The informed consent document cannot give the subject the option of having their data removed from the study database when they withdraw from the study</li> <li>• If subjects who withdraw from the interventional portion of a clinical trial will be asked to allow continued follow-up of clinical outcome information, their informed consent for this limited participation must be obtained on an IRB-approved consent document.</li> </ul> <input type="checkbox"/> N/A – not an FDA regulated clinical trial