

## Guidance for IRB Voting Criteria

This guidance is intended to assist the IRB in determining the correct voting motion on any given transaction review by the full committee. If any requests from the right-hand column are made, the IRB in most circumstances cannot make the motion to APPROVE. This is not a comprehensive list of possible requests that an IRB can make for a given submission. These criteria apply to submissions of new studies, amendments and continuing reviews review by convened IRB

Motion to APPROVE	Motion to NOT APPROVE
<ol style="list-style-type: none"> <li>1. Clarifications that do not impede the Board’s ability to adequately assess the criteria for IRB approval of research at 45 CFR 46.111. These include but are not limited to:</li> <li>2. Correcting grammatical errors throughout IRB documents.</li> <li>3. Formatting changes to IRB documents.</li> <li>4. Adding specifically prescribed language to IRB documents (e.g., consent form, study protocol, inclusion/exclusion criteria, or procedures).</li> <li>5. Providing written responses to questions for which the IRB already knows the answers.</li> <li>6. Providing copies of materials that do not bear on IRB’s determinations regarding 45 CFR 46.111 (“Criteria for IRB approval of research”).</li> <li>7. Adding appropriate information that exists in one or more documents into another document.</li> </ol>	<ol style="list-style-type: none"> <li>1. Provision of new information that bears on IRB’s determinations regarding 45 CFR 46.111 (“Criteria for IRB approval of research”).</li> <li>2. Submission lacks clarity to such a degree that IRB cannot discern purpose, risks, procedures, or other key elements.</li> <li>3. Uses of deception in research that are deemed excessive or unethical.</li> <li>4. Inclusion and/or exclusion of particular subject populations that is deemed unnecessary or unethical.</li> <li>5. Recruitment strategies and/or consenting procedures that are deemed unfeasible and/or unethical.</li> <li>6. Study procedures that are deemed unnecessary and/or unethical.</li> <li>7. Any other issues that make research unfeasible and/or unethical and/or non-adherent with applicable regulations.</li> </ol>