<table>
<thead>
<tr>
<th>Category of Research</th>
<th>Additional Protections</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Research not involving more than minimal risk (45 CFR 46.404)</td>
<td>If appropriate, assure adequate provisions are made for soliciting assent of children and permission of parents or guardians.</td>
</tr>
</tbody>
</table>
| B. Research involving greater than minimal risk but presenting the prospect of direct benefit to individual child participants (45 CFR 46.405) | IRB must determine that:  
  - The research risk is justified by the anticipated benefits to participants;  
  - The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches, and;  
  - Adequate provisions are made for soliciting the assent of children and permission of their parents or guardians. |
| C. Research involving greater than minimal risk and no prospect of direct benefit to individual participants but likely to yield generalizable knowledge about the participant’s disorder or condition (45 CFR 46.406) | An IRB may approve the research only if it finds:  
  - The risk represents a minor increase over minimal risk;  
  - The research presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected dental, psychological, medical, social or educational situation;  
  - The research is likely to yield generalizable knowledge about the participant’s disorder or condition that is of vital importance for understanding or ameliorating it, and;  
  - Adequate provisions are made for soliciting the assent of children and permission of their parents or guardians. |
| D. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407) | An IRB must find that:  
  - The research presents a reasonable opportunity to further understanding, prevention or alleviation of a serious problem affecting the health or welfare of children, and;  
  - The DHHS Secretary will convene a panel of experts in pertinent disciplines to review the research. |

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Division of Compliance