<table>
<thead>
<tr>
<th>Category</th>
<th>Determination</th>
<th>Details</th>
<th>Parental Signature Requirement</th>
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<tbody>
<tr>
<td>1</td>
<td>§46.404 Research not involving greater than minimal risk.</td>
<td>Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.</td>
<td>One parent is sufficient.</td>
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</table>
| 2        | §46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. | (a) The risk is justified by the anticipated benefit to the subjects;  
(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and  
(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408. – One parent signature appropriate | One parent is sufficient.       |
| 3        | §46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. | (a) The risk represents a minor increase over minimal risk;  
(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;  
(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and  
(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408. | Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. |
| 4        | §46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. | (a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and  
(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:  
(1) That the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or  
(2) The following:  
(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;  
(ii) The research will be conducted in accordance with sound ethical principles;  
(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408. | Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. |