



Research with Children Checklist

For research involving subjects under the age of 18

Research involving no greater than minimal risk:

The research presents no greater than minimal risk

Adequate provisions are made for obtaining consent from at least one parent or legally authorized representative (LAR)

Adequate provisions are made for obtaining age - appropriate assent from the children to the extent compatible with their understanding

Research involving greater than minimal risk, but presents the prospect of direct benefit to individual subjects:

The research presents greater than minimal risk

The research presents the prospect of direct benefit to individual subjects



Adequate provisions are made for obtaining consent from all parents or LARs (except when deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for care and custody of the child)

Adequate provisions are made for obtaining age - appropriate assent from the children to the extent compatible with their understanding

The research does not include wards unless the additional considerations for wards below are met

Research not approvable under the above categories :

The research represents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children

The research does not include wards unless the additional considerations for wards below are met

Research involving children who are wards of the state (or any other agency, institution, or entity)

One of the following is true:

s

The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards

An advocate is appointed for each ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis (one individual may serve as advocate for more than one child)

All advocates have the background and experience to act in, and agree to act in, the ipation in the research

The advocates are not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigators, or the guardian organization