



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

The anticipated benefits outweigh the foreseeable risks (i.e., the risks are justifiable given the anticipated benefits)

The ratio of anticipated benefits to risks is at least as favorable to the subject as that presented by available alternative approaches

Adequate provisions are made for obtaining consent from at least one parent or 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 and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject that is of vital importance to the subject's disorder or condition:

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 improvement of the subjects' disorder or condition

The risk represents a minor increase over minimal risk

The research presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations



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:

The research is related to the subjects' status as wards

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 best interest of the child for the duration of the child's participation 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