

**Brown University**

**Appendix A. Children as Subjects**

**Protocol Title:**

**Principal Investigator (PI):**

**IRB Protocol # (if amendment):**

**Date of submission:** Click here to enter a date.

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| **This Appendix must be completed by the PI and included when a proposed study includes** [**children**](#children) **or a study is being amended to add children as participants.**  Federal regulations and Brown University policy require research involving children to be classified into one of four categories. | |
| Please review the four categories of research involving children that may be approved by the IRB, based on degree of risk and benefit to individual subjects, and select which category best describes your protocol: | |
| Category 1 | Research not involving greater than minimal risk [[45 CFR 46.404](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1404)].  (a) adequate provisions are made for soliciting the [assent](#assent) of the children and [permission](#permission) of their [parents](#parents) or [guardians](#guardian), as set forth in [Sec. 46.408](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1408) |
| Category 2 | Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual subject. Research in this category is approvable provided: (a) the risk is justified by the anticipated benefit to the subject; and (b) the relationship of risk to benefit is at least as favorable as any available alternative approach [[45 CFR 46.405](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1405)].   1. risk is justified by the anticipated benefit to the subjects 2. 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 3. adequate provisions are made for soliciting the [assent](#assent) of the [children](#children) and [permission](#permission) of their [parents](#parents) or [guardians](#guardian), as set forth in [Sec. 46.408](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1408) |
| Category 3 | Research involving greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Research in this category is approvable provided:   1. the risk represents a minor increase over minimal risk; 2. 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 settings; and 3. the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition [[45 CFR 46.406](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1406)]. 4. adequate provisions are made for soliciting the [assent](#assent) of the [children](#children) and [permission](#permission) of their [parents](#parents) or [guardians](#guardian), as set forth in [Sec. 46.408](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1408) |
| Category 4 | Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of [children](#children).  Research that is not approvable under [45 CFR 46.404](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1404), [46.405](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1405), or [46.406](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1406) may be conducted or funded by DHHS provided that the IRB, and the Secretary, after consultation with a panel of experts, finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health and welfare of [children](#children).  The panel of experts must also find that the research will be conducted in accordance with sound ethical principles [[45 CFR 46.407](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1407)]. |

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.