

Vulnerable Populations in Research

Purpose

- 1) This policy sets forth both the criteria and process when reviewing research that involves human participants from a vulnerable population. In general, the definition of vulnerable populations in research applies to individuals who lack, or believe they lack, free will or decision-making capacity, either contextually or cognitively, to make informed, voluntary decisions, and are therefore potentially more susceptible to coercion, exploitation, or undue influence.

Policy

- 1) Chapman's Institutional Review Board (IRB) assesses all research involving vulnerable populations ([45 CFR 46.111\(b\)](#); [21 CFR 56.111\(b\)](#)) to ensure that the research includes additional applicable safeguards to help protect the rights and welfare of such participants. The Chapman IRB considers the following groups as vulnerable populations (i.e., individuals with diminished autonomy):
 - a) Pregnant Women, Human Fetuses and Neonates
 - b) Prisoners
 - c) Children
 - d) Individuals with impaired decision-making capacity
 - e) Individuals who are economically, socially, or educationally disadvantaged
 - f) Individuals who, given the circumstances or context, could experience coercion or undue influence or where there is a power dynamic (e.g., researchers and their own children, instructors and their own students, supervisors and their subordinates)
- 2) When either some or all of the research participants are likely to be vulnerable to coercion or undue influence, Chapman's IRB requires one or more individuals who are knowledgeable about or experienced in working with the vulnerable populations to take part in the review of research.
- 3) When the Chapman IRB reviews research enrolling vulnerable populations, Chapman's IRB applies the required additional federal regulations, as well as state and local laws, where applicable.
- 4) The IRB evaluates whether additional safeguards have been incorporated into the research to ensure researchers are protecting the rights and welfare of vulnerable participants.
- 5) The regulations at [45 CFR 46](#) offer additional subparts that stipulate extra protections for enrolling certain vulnerable populations in research, and that also specify requirements for IRBs. When research involves members of one of the Health and Human Services (HHS) recognized vulnerable populations, the IRB and researchers must comply with the following regulations:
 - a) [Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research](#)
 - b) [Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects](#)
 - c) [Subpart D—Additional Protections for Children Involved as Subjects in Research](#)

- i) The Food and Drug Administration (FDA) regulations also require IRBs to determine that research involving children complies with [part 50, subpart D](#).
- 6) Chapman's IRB reviews and approves research enrolling vulnerable populations according to the applicable regulations and subparts; it utilizes checklists when assessing and making determinations.

IRB Review Considerations and Procedures

- 1) When Chapman's IRB reviews research that intends to enroll vulnerable populations, reviewers carefully consider the following elements:
 - a) Strategies to select and recruit participants into the research; issues around informed consent and participants' willingness to volunteer; precautions against coercion, exploitation, and undue influence; and safeguards for confidentiality of data.
 - b) Group characteristics related to economic, social, physical, and environmental conditions, so as to ensure that the research builds in additional safeguards for vulnerable participants.
- 2) PIs are not permitted to exclude certain groups of participants from research that may be beneficial because of a perceived notion that the group has limitations or complications preventing them from enrolling in research.
 - a) To illustrate, PIs should not exclude potential research participants who may be developmentally delayed merely because they may require additional support throughout the consent process.
- 3) Chapman's IRB applies the state or local laws of the jurisdiction where the research is to take place when the IRB reviews research involving vulnerable research participants. That is to say, the Chapman IRB follows state statutes regarding competency to consent for research, emancipated minors, legally authorized representatives, the age of majority for research consent, and the waiver of parental permission for research. Chapman's IRB will consult with Legal Affairs as needed.

Research Involving Pregnant Participants, Human Fetuses and Neonates

- 1) Until 2018, the federal regulations defined pregnant participants as a vulnerable population. The 2018 revisions to Common Rule, however, removed pregnant participants as a vulnerable population in research. This act of revising the definition rectifies the implicit notion that women who are pregnant lack the capacity to make informed, voluntary decisions.
 - a) While the 2018 revisions to Common Rule removed pregnant participants as a vulnerable population in research, there were no similar changes to Subpart B of the Common Rule which addresses Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research. As a result, [Subpart B of 45 CFR 46](#) still stipulates additional safeguards for pregnant participants as well as human fetuses and neonates.
- 2) As stipulated in [45 CFR 46.202\(f\)](#), women are considered to be pregnant if they exhibit "any pertinent signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery."

- 3) According to the federal regulations at [Subpart B of 45 CFR 46](#), Chapman's IRB may approve research involving pregnant participants and fetuses if it concludes that all of the following criteria have been met:
 - a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses ([45 CFR 46.204\(a\)](#));
 - b) Research interventions, tests, or procedures are no more than minimal risk to the pregnant participants or the fetus ([45 CFR 46.204\(b\)](#));
 - c) Research in pregnant participants offers generalizable knowledge that cannot be acquired from nonpregnant participants ([45 CFR 46.204\(d\)](#));
 - d) Each participant who consents to the research understands fully the associated risks and "the reasonably foreseeable impact of the research on the fetus or neonate" ([45 CFR 46.204\(f\)](#));
 - e) Inducements, monetary or otherwise, will not be offered to terminate the pregnancy ([45 CFR 46.204\(h\)](#));
 - f) Individuals engaged in research will not have any part in determining the viability of a neonate ([45 CFR 46.204\(j\)](#)).

Research Involving Prisoners

- 1) For the purposes of this policy, Chapman's IRB does not review research involving prisoners as participants. For investigators wishing to enroll prisoners as research participants, Chapman's IRB requires that an external IRB review and approve the research.
- 2) If a Principal Investigator (PI) discovers that a research participant currently enrolled in a Chapman IRB approved study has become a prisoner, the Chapman IRB will work with the PI to identify an external IRB that could promptly re-review the research in accordance with the requirements of subpart C, if the PI wishes to have the prisoner continue participating in the research.
- 3) An external IRB must re-review the research because the additional protections for research involving prisoners applies in all instances, not just for research that targets prisoners as participants.

Research Involving Children

- 1) In the research setting, [children](#) are considered a vulnerable population.
 - a) Both the Common Rule ([45 CFR 46](#)) and [FDA regulations](#) include [Subpart D: Additional Protections for Children as Research Subjects](#).
 - b) Subpart D establishes risk-benefit categories for research involving children.
 - i) Only research that fits into one of the [first three categories](#) in the reference table below may be approved by the IRB; [the fourth category](#) requires the approval of the Secretary of the Department of HHS.

- 2) California state laws allow minors 12 and older to consent for themselves to participate in research when minors access certain health services that also offer an opportunity to take part in research.
 - a) When research solely involves specific treatments or procedures for which minors can give consent outside the research context (under applicable state and local laws, for example, research on sexually transmitted diseases or pregnancy), these minors would not meet the definition of children as defined at [45 CFR 46.402\(a\)](#). In this instance, the IRB would not apply subpart D when reviewing the research, nor would parental permission (or waiver thereof) be considered. Under these circumstances, minors may consent for themselves to be in research.
- 3) IRB chairs and designated IRB reviewers are required to assess and categorize the risks of research into [one of the allowable categories](#) detailed in the reference table below.
- 4) **Parental Permission**. As stipulated in [45 CFR 46.408\(b\)](#) and [21 CFR 50.55 \(e\)](#), Chapman's IRB must determine that PIs have adequately described the provisions made to solicit and obtain [permission](#) from each child's [parents](#) or [guardians](#).
 - a) When the Chapman IRB approves research to be conducted under [45 CFR 46.404 \(21 CFR 50.51\)](#) or [45 CFR 46.405 \(21 CFR 50.52\)](#), it may find that the [permission](#) of one [parent](#) or [guardian](#) is sufficient.
 - i) Whether the IRB determines that permission should be obtained from one or both [parents](#) will be documented with rationale in the findings section of Cayuse IRB when IRB members record their decision.
 - b) When the IRB approves research conducted under either [45 CFR 46.406](#) or [45 CFR 46.407](#), both parents must give their permission for their child to participate in research, unless:
 - i) One parent is deceased, unknown, incompetent, or not reasonably available; or
 - ii) When only one parent has legal responsibility for the care and custody of the child.
 - (1) **Not reasonably available** means that a parent cannot be present during the informed consent process or is unavailable before research procedures begin. In other words, a parent is not contactable by phone, mail, email or fax, or their whereabouts are unknown.
 - (a) In some cases, **not reasonably available** means that a parent should not be contacted about giving permission for research, owing to the nature of the relationship that exists between the parent and child participant (e.g., domestic violence, harmful situations to the child's health and welfare).
 - c) [Parents](#) or [guardians](#) must receive the elements of informed consent that have been detailed at [45 CFR 46.116\(a\) \(1-8\)](#) and [21 CFR 50.25\(a\) \(1-8\)](#). The IRB will determine whether additional elements are deemed necessary. Regulatory requirements ([45 CFR 46.408\(b\)](#)) for documenting parental permission remain the same as for informed consent.
 - d) Chapman's IRB may waive the requirement to obtain parental permission from parents or legal guardians, provided that the:
 - i) Approved research satisfies the regulatory criteria in [45 CFR 46.116\(f\)\(3\) \(1-4\)](#):
 - (1) The research involves no more than minimal risk to participants.
 - (2) The research could not practicably be carried out without the requested waiver or alteration.

- (3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
- (4) The waiver or alteration will not adversely affect the rights and welfare of participants.
- (5) The research has been designed in such a manner that protects the child participants (e.g., from child neglect or child abuse), and that neither parental nor guardian permission would be a reasonable requirement.
- (6) The appropriate mechanism has been substituted to protect children as research participants, which remains aligned with federal, state, or local laws.
 - (a) [45 CFR 46.408\(c\)](#) provides that in addition to the provisions for waiver contained in [45 CFR 46.116\(a\)](#), if the IRB determines that a research protocol is designed for conditions, or for a research population, for which parental or guardian permission is not a reasonable requirement to protect the participants (e.g., neglected or abused children), it may waive the consent requirements in [Subpart A](#) of this part and [paragraph \(b\)](#) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
 - (b) According to this provision, waiver of parental permission is permitted when it is not a reasonable requirement to protect subjects provided:
 - (i) An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted (e.g., require assent of teenagers who are mature enough to fully comprehend the research activities, appointing an advocate who provides permission for the child, or appointing an assent monitor) and
 - (ii) The waiver is not inconsistent with federal, state, or local law (e.g., PI is requesting waiver of parental permission involving access to FERPA covered records that may not be used without parental permission or requesting a waiver of parental permission for FDA governed research involving children).
- 5) [Assent. 45 CFR 46.408\(e\)](#) dictates that IRBs assume the responsibility for determining how assent from children must be obtained and documented.
 - a) If the research involves children and the investigator has not requested or the IRB has not granted a waiver of alteration of informed consent, permission from a parent (either one or two) and assent of children aged 7 or older must be obtained.
 - b) **Assent Waiver.** Chapman's IRB may waive the requirement to obtain assent if either:
 - i) some or all child participants are incapable of assenting; or
 - ii) the research has the prospect for direct benefit to the participant; or
 - iii) the research qualifies for informed consent to be waived, outlined above in [4\)d\)i](#).
 - c) In certain situations, the IRB may allow Chapman students who are minors to sign the adult consent or parental permission form as opposed to requiring a separate assent document.

- 6) Children who have turned 18 years of age while participating in research are considered adults; for this reason, they must consent to remain enrolled in research. The IRB will determine and document with sufficient detail when re-consenting minors is required.
 - a) If the research procedures are limited to data analysis, re-consent is not required.
 - b) If any research procedures remain for which Chapman's IRB has required informed consent, the 18-year-olds must consent in order to continue their participation in the research. The procedures requiring consent could include but would not be limited to:
 - i) Study visits
 - ii) Continuation of study intervention
 - iii) Collection of data that is identifiable
 - iv) Use of individually identifiable specimens or data under future use provisions of the informed consent form
- 7) **Wards**. Children who are wards of the state, or any other agency, institution, or entity, can be enrolled in research involving greater than minimal risk without the prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition ([45 CFR 46.406](#); [21 CFR 50.53](#)) on the condition that the research is:
 - a) Related to their status as wards; or
 - b) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved are not wards.

If the research proposal fulfills the condition(s) outlined above:

- i) an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in *loco parentis*.
- ii) Advocates must possess the background and experience to act in the best interests of the child while the child participates in the research for its entire duration.
- iii) Advocates must not be associated with the research whatsoever (e.g., with the IRB, researchers, or the guardian organization) except while serving as an advocate.

Participants with Impaired Decision-Making Capacity

- 1) Research warrants special attention when it proposes to enroll participants who have impaired decision-making capacity. Research with this vulnerable population could present risks that might be greater than minimal; the research might not offer the participants any direct benefits. Importantly, the research design could place these vulnerable individuals at greater risk of being coerced or unduly influenced to participate.
- 2) Chapman's IRB reviews and approves research that involves enrolling participants with impaired decision-making capacity by considering the following:
 - a) context in which the research takes place,
 - b) complexity and rigor of the research procedures, and
 - c) monetary compensation, if any, offered.

- 3) When research involves individuals with diminished decision-making capacity, the IRB will review both the research design and the consent process, evaluating whether the proposed research:
 - a) Has an adequate plan to assess participants' capacity to consent.
 - i) The IRB could require PIs to assess participants' competency whenever a possibility exists of enrolling participants with impaired decision-making capacity.
 - ii) Chapman's IRB strongly recommends PIs employ assessment methods that directly evaluate participants' ability to comprehend the proposed study, judge the risks and benefits of the research, and then decide whether to enroll.
 - iii) Even if individuals can provide informed consent, they may refuse to participate in research, despite what their legally authorized representatives (LARs) desire or approve. PIs should not, under any circumstances, coerce or force these individuals to participate.
 - b) Does not present any significant risks, either tangible or intangible.
 - c) Presents some probability of harm or injury and, if so, ensuring that there is greater probability of direct benefit to the participants
 - d) Has devised procedures ensuring that the participants' representatives are well-informed about their obligations and roles for protecting and advocating for participants with impaired decision-making capacity.
- 4) [Decisional impairment](#) consists of participants who:
 - a) Are [incompetent](#) to provide legally effective informed consent to participate in research.
 - b) Are [cognitively impaired](#).
 - c) Have compromised ability to make decisions in their best interests due to:
 - i) being under the influence of or dependent on drugs or alcohol,
 - ii) suffering from degenerative diseases affecting the brains, and
 - iii) severely disabling physical handicaps.
- 5) To give informed consent the participant must be given all relevant information pertinent to the decision and be able to recognize that a decision is needed, and process the information (e.g., discuss it, remember it, evaluate the various factors, and understand the consequences). This process may be compromised due to external factors such as time limitations or stress.
- 6) Chapman's IRB recognizes that research involving participants who are either decisionally impaired or legally incompetent could vary according to circumstances, situations, or degrees of impairment or incompetence.
 - a) Research participants could be considered mentally or cognitively impaired but still be able and have the capacity either to provide informed consent or to refuse to participate in research. In other cases, mentally or cognitively impaired participants are not able to provide informed consent because they lack decisional capacity and, in such cases, researchers would obtain consent from a LAR.
- 7) The IRB will ensure that at least one member who is an expert in decisional impairment, or who works with individuals with limited decision-making capacity, will be present during the review of research. If the IRB does not have this expertise in their membership, they can consult with an individual with similar background.

- a) The IRB may consider, depending on the nature of the research, inviting an individual from the target population, a prospective participant's family members, or a representative of an advocacy group for that population.

Individuals who are Economically, Socially or Educationally Disadvantaged

- 1) The Chapman IRB reviews research involving economically, socially, or educationally disadvantaged populations to ensure that additional protections are included in the study design to minimize risks to the participants.
 - a) Populations that may be considered economically or educationally disadvantaged include, but are not limited to, individuals who live in poverty, who are homeless, who have a low income or limited access to health care, and those who have limited educational attainment.
 - b) Populations that may be considered socially vulnerable can derive from group experiences and typically involve some damage or harms to the community (e.g., indigenous communities, LGBTQ+).
- 2) Special consideration will be given to the informed consent form and process to ensure that individuals have the capacity to understand the information being provided and the voluntary nature of their participation.
- 3) Consideration will be given to both the amount and method of reimbursement to individuals who are economically, socially, and educationally disadvantaged to ensure against undue influence.
- 4) Investigators must ensure submissions include sufficient detail regarding how risks will be mitigated to secure IRB approval for research involving these vulnerable populations.

Individuals who, given the circumstances or context, could experience coercion or undue influence or where there is a power dynamic

- 1) Students
 - a) The IRB is supportive of research involving Chapman students when the risks to participants are minimized, when investigators take special precautions to ensure the rights and welfare of participants are protected, and when students are not compelled to participate in research as part of a class assignment.
 - b) The federal regulations require investigators to obtain consent for participation in research when the possibility of coercion or undue influence is minimized. When investigators recruit Chapman students to participate in research, special consideration should be given to ensure that any possibility of coercion or undue influence is minimized.
 - c) Investigators are encouraged to design research in a way that blinds them to the identity of student participants.
 - d) This could be accomplished through the recruitment of individuals via a participant pool.
 - e) Investigators should generally avoid recruiting students from their classes. Exceptions can be made when research cannot feasibly be completed without recruiting students from the classroom. Please refer to the [Chapman IRB guidance document for additional information on the recruitment of students into research](#).

- f) Non-physical risks are considered when an investigator plans to recruit Chapman students. Non-physical risks include but are not limited to:
- Stigma or reputational harm that could result from a breach in confidentiality or accidental disclosure of confidential information
 - Impact on the student's educational experience
- g) When investigators are recruiting students to participate in research that offers extra credit or rewards for participation, students should also be provided with non-research alternatives involving comparable time and effort.
- h) Students cannot be penalized for declining to participate in research.
- i) The informed consent form should clearly state that the decision not to participate or to withdraw participation will not have any consequences for the student being recruited such as not affecting course grades, class standing, recommendations, access to courses or educational opportunities in the future, or their relationship with an instructor.
- j) Federal Requirements for Students
- i) Federal regulations such as the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA) apply to research involving students, in addition to the Common Rule regulations.
- (1) FERPA requires that schools obtain written consent from parents or students (if the student has reached the age of 18 or is attending an institution of post-secondary education) prior to the release of personally identifiable information from an education record that goes beyond basic directory level information, such as name, telephone number, or dates of attendance.
- ii) PPRA requires that written consent be obtained from students (if they are an adult or emancipated minor) or parents of minors before students can participate in surveys, analysis, or evaluation that involves one or more of the following eight topics:
- (1) Political affiliations or beliefs of the student or the student's parents
 - (2) Mental and psychological problems of the student or the student's family
 - (3) Sex behavior or attitudes
 - (4) Illegal, anti-social, self-incriminating or demeaning behavior
 - (5) Critical appraisals of other individuals with whom respondents have close family relationships
 - (6) Legally recognized privileged or analogous relationships, such as those with lawyers, physicians, and ministers
 - (7) Religious practices, affiliations, or beliefs of the student or student's parents
 - (8) Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

2) Employees

- a) The IRB is supportive of research involving Chapman employees when the risks to participants are minimized and when investigators take special precautions to ensure the rights and welfare of participants are protected.
- b) The federal regulations require investigators to obtain consent for participation in research when the possibility of coercion or undue influence is minimized. When investigators recruit Chapman employees to participate in research, special consideration should be given to ensure that any possibility of coercion or undue influence is minimized.
- c) Investigators should design research in a way that blinds them to the identity of the employees who participate in research.
- d) Employees who decline to participate in research should not be penalized through performance evaluations or consideration of job advancement. Alternatively, participation of employees in research should not bestow any type of occupational advantage over staff who decline participation.
- e) The informed consent form should clearly state that the decision not to participate or to withdraw participation will not have any negative consequences for the individual being recruited such as consideration of bonus, promotion, and work evaluations. Please refer to the [Chapman IRB guidance document for additional information on the recruitment of employees into research](#).

Reference Table: Allowable Research Involving Children

ALLOWABLE RESEARCH INVOLVING CHILDREN			
45 CFR 46 (OHRP); 21 CFR 50 (FDA)	CATEGORY	REQUIREMENTS	PARENTAL PERMISSION
46.404 ; 50.51	Research not involving greater than minimal risk	<p>The IRB must determine the following before children may be involved as participants in research:</p> <p>Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 46.408 and 50.55.</p> <p>Wards of State: There are not any additional regulatory protections to apply when wards of state enroll in research that the IRB has approved under this category.</p>	<p>Permission from one parent may be sufficient</p> <p>Wards of State: States may stand in <i>loco parentis</i></p>
46.405 ; 50.52	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects	<p>a. The risk is justified by the anticipated benefit to the subjects;</p> <p>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</p> <p>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 and 50.55.</p> <p>Wards of State: There are not any additional regulatory protections to apply when wards of state enroll in research that the IRB has approved under this category.</p>	<p>Permission from one parent may be sufficient</p> <p>Wards of State: States may stand in <i>loco parentis</i></p>
46.406 ; 50.53	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	<p>a. The risk represents a minor increase over minimal risk;</p> <p>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;</p> <p>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</p> <p>d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in 46.408 and 50.55.</p>	<p>Permission must be obtained from both parents</p>

		<p>Wards of State: The IRB may approve research under this category if the research is either related to their status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as children are not wards.</p> <p>The IRB must request that an advocate be appointed for each child who is a ward. The advocate will serve in addition to any other individual acting on behalf of the child as guardian.</p>	
<p>46.407; 50.54</p>	<p>Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children</p>	<p>a. 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</p> <p>b. The Secretary of DHHS or Commissioner of Food and Drugs for the FDA, 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:</p> <ol style="list-style-type: none"> 1. That the research in fact satisfies the conditions of 46.404 and 50.51, 46.405 and 50.52, or 46.406 and 50.53, as applicable, OR 2. The following: <ol style="list-style-type: none"> i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and 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 and 50.55. <p>Wards of State: The IRB may approve research under this category if the research is either related to their status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as children are not wards.</p> <p>The IRB must request that an advocate be appointed for each child who is a ward. The advocate will serve in addition to any other individual acting on behalf of the child as guardian.</p>	<p>Permission must be obtained from both parents</p>

Revision history:

May 2023 - document version date appearing more clearly in the footer

17Jun2022 - original publication date

Original version: 17Jun2022