

	SUBJECT POPULATION			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	7.01	02.12.2020	7.01	02.07.2020

SUBJECT POPULATION

It is the responsibility of the principal investigator to identify the sources of potential subjects; describe the characteristics of the subject population, such as their anticipated number, age, sex, ethnic background, and state of health; identify the criteria for inclusion and exclusion; explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, institutionalized individuals (mentally disabled, prisoners or others) especially those whose ability to give voluntary informed consent may be in question. In addition, the rationale for involvement of disproportionate numbers of racial or ethnic minorities, the aged, or persons of low socioeconomic status must be stated. Likewise, the lack of inclusion of these groups, including children, must be explained.

Community-based participatory research also requires additional considerations in reviewing the protocol. Research which involves community members in the research process must be fully described in the application. Review by the Board will include the design and implementation of research and the dissemination of results. IRB members are educated in this type of research, and members or outside consultants with expertise in this area are called upon for their input.

VULNERABLE POPULATIONS

Subjects from vulnerable populations are those whose ability to give voluntary informed consent may be in question. Examples of vulnerable populations are children, pregnant women, fetuses, terminally-ill patients, prisoners, institutionalized persons (mentally ill), wards, and individuals who might be under psychological pressure to volunteer. If vulnerable populations are to be used, investigators must deal thoroughly with the potential for risk. It should be understood that the definition of “minimal risk” for vulnerable populations is different than for non-vulnerable populations. Consultation with the IRB Office on this issue is strongly urged if vulnerable populations are being asked to participate as research subjects. Federal regulations require additional IRB considerations if vulnerable populations of subjects are used.

Children as Research Subjects

Any proposed research in which children (individuals less than 18 years of age) are enrolled must meet the standards of 45CFR46, Subpart D and 21CFR50, Subpart D.

45CFR46, Subpart D

§46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that 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](#).

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for

the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

- (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](#).

§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.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

- (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](#).

§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.

HHS will conduct or fund research that the IRB does not believe meets the requirements of [§46.404](#), [§46.405](#), or [§46.406](#) only if:

- (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](#).

§46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with [§46.116](#) of [Subpart A](#).

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by [§46.116](#) of [Subpart A](#), that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under [§46.404](#) or [§46.405](#). Where research is covered by [§§46.406](#) and [46.407](#) and permission is to be obtained from parents, 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.

(c) In addition to the provisions for waiver contained in [§46.116](#) of [subpart A](#), if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, 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.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by [§46.117](#) of [subpart A](#).

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under [§46.406](#) or [§46.407](#) only if such research is:

- (1) Related to their status as wards; or
- (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under [paragraph \(a\)](#) of this section, the IRB shall require appointment of an advocate for each child who is a 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. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

21CFR50, Subpart D

§50.51 Clinical investigations not involving greater than minimal risk.

Any clinical investigation within the scope described in §§50.1 and 56.101 of this chapter in which no greater than minimal risk to children is presented may involve children as subjects only if the IRB finds that:

- (a) No greater than minimal risk to children is presented; and
- (b) Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as set forth in §50.55.

§50.52 Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects.

Any clinical investigation within the scope described in §§50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, may involve children as subjects only if the IRB finds that:

- (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 §50.55.

§50.53 Clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition.

Any clinical investigation within the scope described in §§50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, may involve children as subjects only if the IRB finds that:

- (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 that is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- (d) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians as set forth in §50.55.

§50.54 Clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

If an IRB does not believe that a clinical investigation within the scope described in §§50.1 and 56.101 of this chapter and involving children as subjects meets the requirements of §50.51, §50.52, or §50.53, the clinical investigation may proceed only if:

- (a) The IRB finds that the clinical investigation 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 Commissioner of Food and Drugs, 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, determines either:
 - (1) That the clinical investigation in fact satisfies the conditions of §50.51, §50.52, or §50.53, as applicable, or
 - (2) That the following conditions are met:
 - (i) The clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
 - (ii) The clinical investigation will be conducted in accordance with sound ethical principles; and

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in §50.55.

§50.55 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart D, the IRB must determine that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent.

(b) In determining whether children are capable of providing assent, the IRB must take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in clinical investigations under a particular protocol, or for each child, as the IRB deems appropriate.

(c) The assent of the children is not a necessary condition for proceeding with the clinical investigation if the IRB determines:

(1) That the capability of some or all of the children is so limited that they cannot reasonably be consulted, or

(2) That the intervention or procedure involved in the clinical investigation holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the clinical investigation.

(d) Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that:

(1) The clinical investigation involves no more than minimal risk to the subjects;

(2) The waiver will not adversely affect the rights and welfare of the subjects;

(3) The clinical investigation could not practicably be carried out without the waiver; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) In addition to the determinations required under other applicable sections of this subpart D, the IRB must determine, in accordance with and to the extent that consent is required under part 50, that the permission of each child's parents or guardian is granted.

(1) Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for clinical investigations to be conducted under §50.51 or §50.52.

(2) Where clinical investigations are covered by §50.53 or §50.54 and permission is to be obtained from parents, 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.

(f) Permission by parents or guardians must be documented in accordance with and to the extent required by §50.27.

(g) When the IRB determines that assent is required, it must also determine whether and how assent must be documented.

§50.56 Wards.

(a) Children who are wards of the State or any other agency, institution, or entity can be included in clinical investigations approved under §50.53 or §50.54 only if such clinical investigations are:

- (1) Related to their status as wards; or
- (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the clinical investigation is approved under paragraph (a) of this section, the IRB must require appointment of an advocate for each child who is a ward.

- (1) The advocate will serve in addition to any other individual acting on behalf of the child as guardian or in loco parentis.
- (2) One individual may serve as advocate for more than one child.
- (3) The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the clinical investigation.
- (4) The advocate must not be associated in any way (except in the role as advocate or member of the IRB) with the clinical investigation, the investigator(s), or the guardian organization.

LSUHSC-NO adopts the standards of these regulations and protections as its own.

Prisoners as Research Subjects

Any research proposed in which prisoners (individuals whose freedom is limited through governmental edict) must meet the standards of 45CFR46 Subpart C. LSUHSC-NO adopts the standards of these regulations and protections as its own.

Fetuses and Pregnant Women

Pregnant women are recognized as a vulnerable population because of the additional health concerns during pregnancy. There is also a need to avoid unnecessary risk to the fetus. Any research proposed in which fetuses and pregnant women are the subject of or are participants in the research must meet the standards of 45CFR46 Subpart B. LSUHSC-NO adopts the standards of these regulations and protections as its own.

Students

Any research proposed that will incorporate students as research subjects must follow federal regulations protecting those students and their families as explained in the “Family Educational Rights and Privacy Act Regulations (FERPA)” at 34CFR Part 99: (see <http://www2.ed.gov/policy/gen/reg/ferpa/index.html>) and under Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98) (see

<http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html>). The process to comply with FERPA will be implemented at the time of Departmental Review. As part of this process the IRB consults with the LSUHSC-NO Registrar, the office at LSUHSC-NO responsible for FERPA interpretation as related to LSUHSC-NO students.

There is in place a process to grant exceptions to parental or student consent to release student records for research. This responsibility is delegated to the IRB Chair or Vice-Chair. An educational agency or institution may disclose personally-identifiable information from an education record of a student without consent if the disclosure is part of an agreement between organizations or researchers conducting studies for, or on behalf of, educational agencies or institutions to: develop, validate, or administer predictive tests; administer student aid programs; or improve instruction.

A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the Organization or Researcher conducting the research that specifies: the determination of the exception; the purpose, scope, and duration of the study; the information to be disclosed; that information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in Department of Education regulations on re-disclosure and destruction of information; that the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the Organization with legitimate interests; that the Organization is required to destroy or return all personally-identifiable information when no longer needed for the purposes of the study; and the time period during which the Organization must either destroy or return the information.

Education records may be released without consent under FERPA if all personally-identifiable information has been removed including: student's name and other direct personal identifiers, such as the student's social security number or student number; indirect identifiers, such as the name of the student's parent or other family members, the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable, and date and place of birth and mother's maiden name; biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting; other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

The IRB has in place a process to comply with the Protection of Pupil Rights Amendment.

For research funded by the U.S. Department of Education, no student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following: political affiliations; mental and psychological problems potentially embarrassing to the student or his or her family; sex behavior and attitudes; illegal, anti-social, self-incriminating and demeaning behavior; critical appraisals of other individuals with whom the student has close family relationships; legally-recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers; religious practices, affiliations, or beliefs of the student or student's parent; income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

Prior consent means prior consent of the student, if the student is an adult or emancipated minor; or prior

written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation.

For research not funded by the US Department of Education, the IRB must verify compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

- the right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student;
- any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received;
- arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items): political affiliations or beliefs of the student or the student's parent; mental or psychological problems of the student or the student's family; sex behavior or attitudes; illegal, anti-social, self-incriminating, or demeaning behavior; critical appraisals of other individuals with whom respondents have close family relationships; legally-recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers; religious practices, affiliations, or beliefs of the student or student's parent; income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.
- The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student.
- Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
- The administration of physical examinations or screenings that the school or agency may administer to a student.
- The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.
- The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.
- Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

For research funded by the National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants.

Employees/students of LSUHSC-NO

Under most circumstances, employees/students at LSUHSC-NO may not participate in projects where the investigators, in their roles of faculty members or supervisors, are involved in grading the academic or clinical performance of, or otherwise evaluating, the subjects. Research involving students/employees

as subjects is reviewed on a case-by-case basis. The single most important factor in considering exceptions to the above rule is the complete absence of either coercion or the perception of coercion by the students/employees who are asked to participate. Other factors affecting this decision of exception include: having a mechanism to assure anonymity; having a method to assure that no penalties can be imposed on students/employees who refuse to participate, etc. It is unusual for the IRB to approve projects utilizing students/employees that are considered greater than minimal risk. The request to include LSUHSC-NO students/employees must be included in the application project summary.

COMMUNITY MEMBERS INVOLVED IN RESEARCH DESIGN AND IMPLEMENTATION

In certain cases, the design, conduct, and dissemination of results of research can be enhanced when individuals from the community where the research is taking place are involved. LSUHSC-NO supports researchers who wish to conduct research that involve community members.

The study team should consider and include the following information in the IRB application:

- A description of how the community member(s) will be involved in the design and conduct;
- Researchers and community members should work to identify any potential risks or issues that are specific to the community, and appropriate measures should be identified to minimize the risks;
- Have a plan for dissemination of results to the community; and
- Researchers should consider benefits that can be provided to the communities involved to foster productive partnerships.

IRB staff members are available to assist with education, questions related to the project, and submission requirements related to this type of research. This includes:

- Regulatory considerations related to study team engagement, performance sites, and vulnerable population involvement;
- Education and training requirements for the study team members;
- Any IRB-related agreements that should be in place (e.g. IAA or IIA); and,
- Periodic evaluation of the study to ensure federal regulations, and policies and procedures as being followed as well as ensuring community involvement is being facilitated as the study was designed.