

SOP 14D v.2

10/1/13

**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &
IMPLEMENTATION**

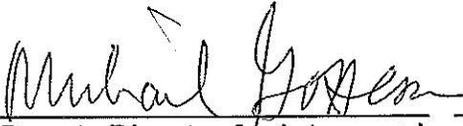
OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

SOP Number: SOP 14D v.2

SOP Title: Research Involving Children

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB
Chairs, IRB Administrators, Protocol Navigators**

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Research

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SOP 14D RESEARCH INVOLVING CHILDREN

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SOP 14D RESEARCH INVOLVING CHILDREN

INTRODUCTION

This SOP highlights the most common issues that arise at NIH with regard to research with children, but the SOP is not a complete set of regulatory requirements. Therefore, please refer to 45 CFR Subpart D, attached as Appendix A, which is hereby incorporated into this SOP.

14D.1 PURPOSE

This SOP discusses the requirements for NIH investigators, IRBs and others when conducting and reviewing research involving children.

14D.2 POLICY

- A. The NIH HRPP follows the requirements of this SOP which are consistent with Federal Regulations for the Protection of Human Subjects (45 CFR 46) Subpart D “Additional Protections for Children Involved as Subjects in Research” (See Appendix A). For the applicable requirements of the Food and Drug Administration (FDA), see 21 CFR 50, Subpart D – Additional Safeguards for Children in Clinical Investigations (See Appendix B- Links to web sites). The requirements of this SOP are in addition to those imposed under other subparts of 45 CFR 46 and other relevant SOPs.
- B. Children must be included in research unless there are scientific justifications not to include them (see 14D.5.1.B, below).
- C. There are exemptions that may not apply to research involving children. The exemption for research involving the use of educational tests (45 CFR 46.101(b)(2)) is narrowed in scope when applied to involving children (for more information, see SOP 6 “Determinations, IMade by the Office of Human Subjects Research Protections

(OHSRP)"). The other five exemptions found at 46.101(b) apply to research involving children in the same way that they apply to research involving adults.

- D. The Secretarial waiver of informed consent in certain emergency research may be applicable to research involving children (see SOP 12 "Requirements of Informed Consent").

14D.3 DEFINITIONS

- A. **Advocate** is 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 investigators(s), or the guardian organization.
- B. **Assent** means a child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent (45 CFR 46.402(b)).
- C. **Benefit** is a valued or desired outcome of the research for the child subjects.
- D. **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 (45 CFR 46.402(a)).
- 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 (45 CFR 46.402(e)).

- F. **Minimal Risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (see 45 CFR Part 46 102(i)).
- G. **Parent** means a child's biological or adoptive parent (45 CFR 46.402(d)).
- H. **Permission** means the agreement of parent(s) or guardians(s) to the participation of their child or ward in research. (45 CFR 46.402(c)).
- I. **Risk** is the probability of harm (physical, emotional, social, or economic). The probability of harm may vary from minimal to substantial.
- J. **Secretary** means the Secretary of Health and Human Services and any other officer or employee of DHHS to whom authority has been delegated.
- K. **Ward** means a child who is placed under the protection of and in the legal custody of the State or other agency, institution, or entity (including guardians), consistent with applicable State or local law.

14D.4 RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS WHEN APPLYING FOR INITIAL IRB REVIEW FOR RESEARCH INVOLVING CHILDREN

When conducting research protocols involving children, PIs shall provide information to the IRB required by this and other HRPP SOPs and the NIH Intramural Clinical Initial Protocol Application, including the Application's Supplement D (Research Involving Children).

14D.5 RESPONSIBILITIES OF NIH IRBS REGARDING REVIEW OF RESEARCH INVOLVING CHILDREN

14D.5.1 APPROVAL OF RESEARCH INVOLVING CHILDREN

An IRB may approve research involving children only if it has determined and documented in its minutes that:

- A. The research is scientifically sound and significant.
- B. In keeping with ethical guidelines on research involving children, when appropriate, earlier studies have been conducted first on animals and adult humans, and then on older children before involving younger children and infants. Investigators must provide and IRBs are responsible for approving ethical and scientific justifications for recruiting children within the age range stipulated in the protocol.
- C. Risks to children are minimized using the safest procedures available consistent with sound research design and, whenever feasible, using procedures performed for diagnostic or treatment purposes.
- D. Adequate provisions are made to protect the privacy of children and their parents or guardians, and to maintain the confidentiality of data.
- E. Subjects will be selected in an equitable manner; and
- F. The conditions of all other applicable sections of this SOP are met.

14D.5.2 ALLOWABLE CATEGORIES OF RESEARCH

- A. The HHS federal regulations permit four categories of research involving children:
1. Category 1. 45 CFR 46.404, Research not involving greater than minimal risk
 2. Category 2. 45 CFR 46.405, Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects
 3. Category 3. 45 CFR 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
 4. Category 4. 45 CFR 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.
- B. Each category imposes special requirements upon the IRB's reviews of any study involving children. The IRB is responsible for determining into which of the four categories of research the study belongs and documenting in the minutes and IRB records its rationale for this choice. The IRB should consult the PI in making this determination.
- C. In the case of Category 4 (45 CFR 46.407), which requires a determination by the Secretary, DHHS, the IRB will forward the approved research protocol to the Director, Office of Human Subjects Research Protections (OHSRP) who will present it to the Deputy Director of Intramural Research (DDIR) (the Institutional Official) or designee for approval. Upon approval

by the DDIR, OHSRP will forward the protocol to the Office for Human Research Protections (OHRP) for review by the Secretary, DHHS and, if appropriate, the Commissioner, FDA per 21 CFR 50.54.

- D. For FDA requirements regarding research in children see 21 CFR 50, Subpart D, Additional Safeguards for Children in Clinical Investigations (See Appendix B- Links to web sites).

14D.6 RESPONSIBILITIES OF NIH PIS AND IRBS REGARDING REQUIREMENTS FOR OBTAINING AND DOCUMENTING PERMISSION BY PARENTS OR GUARDIANS

14D.6.1 OBTAINING OR WAIVING PARENTAL PERMISSION

In addition to the other applicable sections of Subpart D, the IRB must determine, in accordance with and to the extent that is required by 46.116, as described in SOP 12 (“Requirements of Informed Consent”), that adequate provisions have been made for soliciting the permission of each child’s parent or guardian. This and additional requirements for obtaining permission are described in 45 CFR 46.408(b). When parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research conducted under regarding categories 1 and 2 (see above 14D.5.2) and the IRB should document this finding. IRBs should also document if consent from both parents is required. Where research is conducted under categories 3 and 4 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. If an IRB chooses to waive the consent requirements of Subpart A and 46.408(b), the requirements of 45 CFR 46.408(c) must be followed.

14D.6.2 DOCUMENTATION OF PARENTAL PERMISSION

Permission from parents or legal guardians must be documented in accordance with and to the extent required by 46.117 (see SOP 12 “Requirements of Informed Consent”), including possible waiver of documentation of informed consent (46.408(d)).

14D.7 RESPONSIBILITIES OF NIH PIS AND IRBS REGARDING REQUIREMENTS FOR OBTAINING AND DOCUMENTING ASSENT BY CHILDREN

14D.7.1 PI RESPONSIBILITIES

- A. Every protocol involving children shall include a discussion of how assent will be obtained, if at all, for that particular study. This may take the form of a description of how information will be verbally communicated to the child or a sample written assent document appropriate to the age and comprehension level of the children to be enrolled. A written assent should be obtained when the IRB determines it to be a meaningful process within the context of the particular research study. For subjects at the NIH Clinical Center, NIH form 2514-2 (Attachment A) is used.
- B. If obtaining assent is not anticipated in the protocol, the PI is obligated to justify to the IRB why assent (written or oral) is not possible.

14D.7.2 IRB RESPONSIBILITIES

- A. The IRB shall determine that adequate provisions are made for:
 - 1. Soliciting the assent of the children when in the determination of the IRB they are capable of assent, see **14D.7.2.B**, below, and Appendix C (Guidelines on Children’s Assent). This appendix is based on the NIH Medical Administrative Series 92-5 “Research Involving

Children and Children’s Assent.” (See Appendix B- Links to Web sites.)

2. Considering the objections to participation by a child who is capable of assent. A child’s objections(s) should be binding unless the research holds out a prospect of direct benefit that is important to the health and wellbeing of the child and that is available only in the context of research.
 3. Monitoring the solicitation of assent when appropriate.
- B. 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 study, or for each child, as the IRB deems appropriate.
1. The assent of child research subjects is not a necessary condition for proceeding with the research in the infrequent circumstances in which the IRB determines that (i) some of all of the children’s capabilities are so limited that they cannot reasonably be consulted, or (ii) 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.
 2. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement in circumstances in which consent may be waived in accord with 45 CFR 46.116 (found in the provisions in SOP 12 “Requirements of Informed Consent”). (45 CFR 46.408(a)).

14D.7.3 DOCUMENTATION OF ASSENT

If an IRB determines that assent will be obtained, it shall determine whether, and how, it shall be documented (46 CFR 46.408(e)).

- A. If assent is obtained verbally, this should be documented on the research consent form signed by the parents/guardians.

- B. When a written assent document is used, the signatures of the child and investigator should be documented on the assent form. The signatures of the parent(s)/guardian(s), investigator and a witness (when applicable) will be documented on the consent form (for more information see SOP 12, “Requirements for Informed Consent”).

14D.7.4 RECONSENT OF MINORS WHO REACH AGE OF CONSENT WHILE ON A RESEARCH STUDY

- A. Unless the IRB determines that the requirements for obtaining informed consent can be waived, the PI should seek and obtain the legally effective informed consent of the now-adult subject.

- B. The PI should seek and obtain the legally effective informed consent of the now-adult subject even if the research does not involve any ongoing interactions or interventions with the subject, but continues to meet the regulatory definition of “human subjects research” (e.g., it involves the continued analysis of identifiable specimens or data). In these circumstances, if appropriate, the IRB may consider a waiver under 45 CFR 46.116 (d).

14D.8 CHILDREN WHO ARE WARDS

- A. Children who are wards of the State or any other agency, institution, or entity can be included in approved Category 3 (45 CFR 46.406) or Category 4 (45 CFR 46.407) research 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 meets the condition(s) above in paragraph A, the IRB must 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 must 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. (45 CFR 46.409).

LIST OF APPENDICES

Appendix A- 45 CFR Subpart D – Additional Protections for Children Involved as Subjects in Research

Appendix B- Links to web sites

Appendix C- Guidelines on Children's Assent

LIST OF ATTACHMENTS

Attachment A: NIH Form 2514-2

APPENDIX A- 45 CFR SUBPART D – ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED AS SUBJECTS IN RESEARCH

Subpart D	Additional Protections for Children Involved as Subjects in Research
	Source: 48 FR 9818, March 8, 1983, unless otherwise noted.

§46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under [paragraph \(e\)](#) of [§46.101](#) of [subpart A](#), waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at [§46.101\(b\)\(1\)](#) and [\(b\)\(3\)](#) through [\(b\)\(6\)](#) are applicable to this subpart. The exemption at [§46.101\(b\)\(2\)](#) regarding educational tests is also applicable to this subpart. However, the exemption at [§46.101\(b\)\(2\)](#) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in [paragraphs \(c\)](#) through [\(i\)](#) of [§46.101](#) of [subpart A](#) are applicable to this subpart.

[48 FR 9818, Mar.8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991.]

§46.402 Definitions.

The definitions in [§46.102](#) of [subpart A](#) shall be applicable to this subpart as well. In addition, as used in this subpart:

(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.

§46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under [this part](#), each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§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.

APPENDIX B - LINKS TO WEB SITES

- A. 45 CFR 46 Subpart D “Additional Protections for Children Involved as Subjects in Research”:
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

- B. 21 CFR 50, Subpart D – Additional Safeguards for Children in Clinical Investigations

- C. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.19.4>

- D. NIH Medical Administrative Series 92-5 “Research Involving Children and Children’s Assent.”

- E. <http://cc-internal.cc.nih.gov/policies/PDF/M92-5.pdf>

- F. OHSR Special Protections for Children as Research Subjects.
<http://www.hhs.gov/ohrp/policy/populations/children.html>

- G. OHSR Children Involved as Subjects in Research: Guidance on the HHS 45.CFR.46.407 (“407”) Review Process.
http://www.hhs.gov/ohrp/policy/populations/guidance_407process.html

- H. OHSR Research with Children FAQs.
<http://answers.hhs.gov/ohrp/categories/1570>

APPENDIX C: GUIDELINES ON CHILDREN'S ASSENT

(This is adapted from MAS 92-5 – “Research Involving Children and Children’s Assent to Research”)

The following guidelines are intended to assist the investigator and the IRB to formulate assent procedures that will best serve the needs of the children who participate in a protocol.

A. Critical to the assent process is consideration of the maturation level of the children’s thought processes and capacities for comprehension:

1. A child with normal cognitive development becomes capable of meaningful assent at about the age of 7 years, although there is a wide range of variation.
2. Time is not similarly comprehended at all ages. A discussion of time requirements in a research protocol must be appropriate to the child's level of understanding.
3. Age is only a gross index of mental level and reasoning capacity.
4. A child's level of comprehension and reasoning will be altered by states of anxiety, and physical and emotional disturbances.

B. The protocol should be explained in such a manner that the child can provide a meaningful and informed assent. This explanation should include:

1. A reason for the child being at the research facility; i.e., relate the child's presence at the hospital to something meaningful in his/her experience.
2. Realistic expectations concerning what a child will experience in the hospital, including:
 - a. staying in bed....or not

- b. going home....or staying in the hospital
 - c. separation from the parents/friends or not
 - d. supervision by doctors and nurses
 - e. presence of other patients.
3. A description of specific procedures and the immediate consequences of those procedures, e.g., pain, falling asleep, medication by a tube put into the arm, how the child will look different or how his/her body might be changed as result of participation in the study, etc.
4. An explanation of the reason for a study and the hoped for benefits to the child, or how the study accomplishes benefits for other children.
- C. Children involved research which holds no anticipated benefit to them as individuals may withdraw or choose not to participate in the study at all. Since children (to age 7, for example) may not be accustomed to this type of control over what they are permitted to do, this right to dissent, if granted, may be misinterpreted. It is the investigator's responsibility to guide both the child and parents/guardians in this decision.

SOP 14D - Attachment A

NIH HRPP SOP 14D v2 10-1-2013

MEDICAL RECORD	MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Attach to NIH-2514-2, Consent to Participate in a Clinical Research Study
-----------------------	--

INSTITUTE:

STUDY NUMBER:

PRINCIPAL INVESTIGATOR:

STUDY TITLE:

Initial Review Approved by the IRB on _____
[Document Description]

Date Posted to Web: _____

Revision Copy

PATIENT IDENTIFICATION DHHS/NIH/OD/OIR/OHSRP	MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY NIH-2514-2 (10-09) P.A.: 09-25-0099 File in Section 4: Protocol Consent (#)
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NIH HRPP SOP 14D v2 10-1-2013

MEDICAL RECORD

CONTINUATION SHEET for either:

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER:

CONTINUATION: page 2 of X pages

Revision Copy

PATIENT IDENTIFICATION

DHHS/NIH/OD/OIR/OHSRP

CONTINUATION SHEET for either:

NIH-2514-1 (10-84)

NIH-2514-2 (10-84)

P.A.: 09-25-0099

NIH HRPP SOP 14D v2 10-1-2013	
MEDICAL RECORD	MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY NUMBER: _____

CONTINUATION: page 3 of X pages

Revision Copy

I have had this study explained to me in a way that I understand, and I have had the chance to ask questions. I agree to take part in this study.

Signature of Minor Patient: _____ Date: _____

Print Name: _____

Signature of Investigator: _____ Date: _____

Print Name: _____

PATIENT IDENTIFICATION	MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY NIH-2514-2 (10-09) P.A.: 09-25-0099 File in Section 4: Protocol Consent
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DHHS/NIH/OD/OIR/OHSRP