

VAMHCS Office of Research Compliance

INFORMED CONSENT FORM REVIEW CHECKLIST SELF-ASSESSMENT TOOL

GENERAL INFORMATION

Principal Investigator		
E-mail Address		
Sub-Investigator(s)		
Key Personnel/Function	Personnel	Function
IRB Panel		
IRB Protocol Number		
Study Title		
School/Center/Institution <i>Please check one:</i>	<input type="checkbox"/> SOM <input type="checkbox"/> Dental <input type="checkbox"/> Pharm <input type="checkbox"/> Nursing <input type="checkbox"/> SW <input type="checkbox"/> CVD <input type="checkbox"/> MPRC <input type="checkbox"/> IHV <input type="checkbox"/> GCC <input type="checkbox"/> GCRC	
Subject Population <i>Please check all that apply:</i>	<input type="checkbox"/> Geriatric <input type="checkbox"/> Pregnant Women <input type="checkbox"/> Pediatric <input type="checkbox"/> Prisoner <input type="checkbox"/> Psychiatric <input type="checkbox"/> Mentally Disabled <input type="checkbox"/> Handicapped <input type="checkbox"/> Veteran <input type="checkbox"/> Employee/Student <input type="checkbox"/> Community	
Sponsor <i>Please check one:</i>	<input type="checkbox"/> Industry <input type="checkbox"/> Government <input type="checkbox"/> Internal/Department <input type="checkbox"/> Foundation <input type="checkbox"/> Other: _____	
Funding Source <i>Please check one:</i>	<input type="checkbox"/> Industry <input type="checkbox"/> Government <input type="checkbox"/> Internal/Department <input type="checkbox"/> Foundation <input type="checkbox"/> Other: _____	
Person Completing Checklist		
Date Checklist Completed		

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TITLE 21 -- FOOD AND DRUGS

CHAPTER I -- FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 50 -- PROTECTION OF HUMAN SUBJECTS

Subpart B -- Informed Consent of Human Subjects

Sec. 50.20 General requirements for informed consent.

An investigator shall seek the legally effective informed consent of the subject or the subject's legally authorized representative only under circumstances that:

- _____ Provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate
- _____ Minimize the possibility of coercion or undue influence

Additionally,

- _____ The information that is given to the subject or the representative shall be in language understandable to the subject or the representative
- _____ No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights
- _____ No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence

VAMHCS Office of Research Compliance**Sec. 50.25 Elements of informed consent.**

(a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:

- _____ (1) A statement that the study involves research
 - _____ An explanation of the purposes of the research
 - _____ The expected duration of the subject's participation
 - _____ A description of the procedures to be followed
 - _____ Identification of any procedures which are experimental
- _____ (2) A description of any reasonably foreseeable risks or discomforts to the subject
- _____ (3) A description of any benefits to the subject or to others which may reasonably be expected from the research
- _____ (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- _____ (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
 - _____ A statement that notes the possibility that the Food and Drug Administration may inspect the records
- _____ (6) For research involving more than minimal risk:
 - _____ An explanation as to whether any compensation is available if injury occurs
 - _____ An explanation as to whether any medical treatments are available if injury occurs
 - _____ If so, what they consist of, or where further information may be obtained
- _____ (7) An explanation of whom to contact for answers to pertinent questions about the research
 - _____ An explanation of whom to contact for answers to pertinent questions about research subjects' rights
 - _____ An explanation of whom to contact for answers to pertinent questions about whom to contact in the event of a research-related injury to the subject
- _____ (8) A statement that participation is voluntary
 - _____ A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
 - _____ A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

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(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

- _____ (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
- _____ (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- _____ (3) Any additional costs to the subject that may result from participation in the research
- _____ (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- _____ (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
- _____ (6) The approximate number of subjects involved in the study.

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Sec. 50.27 Documentation of informed consent.

(a) Except as provided in Sec. 56.109(c), informed consent shall be documented by the use of a written consent form:

- _____ Approved by the IRB
- _____ Signed and dated by the subject or the subject's legally authorized representative at the time of consent
- _____ A copy shall be given to the person signing the form

(b) Except as provided in Sec. 56.109(c), the consent form may be either of the following:

_____ (1) A written consent document that embodies the elements of informed consent required by Sec. 50.25. *This form may be read to the subject or the subject's legally authorized representative*, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

_____ (2) A short form written consent document stating that the elements of informed consent required by Sec. 50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used,

- _____ There shall be a witness to the oral presentation
- _____ The IRB shall approve a written summary of what is to be said to the subject or the representative
- _____ Only the short form itself is to be signed by the subject or the representative
- _____ The witness shall sign both the short form and a copy of the summary
- _____ The person actually obtaining the consent shall sign a copy of the summary
- _____ A copy of the summary shall be given to the subject or the representative
- _____ A copy of the short form shall be given to the subject or the representative

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Subpart D -- Additional Safeguards for Children in Clinical Investigations

Sec. 50.50 IRB duties.

In addition to other responsibilities assigned to IRBs under this part and part 56 of this chapter, each IRB must review clinical investigations involving children as subjects covered by this subpart D and approve only those clinical investigations that satisfy the criteria described in Sec. 50 .51, Sec. 50 .52, or Sec. 50 .53 and the conditions of all other applicable sections of this subpart D.

Sec. 50.51 Clinical investigations not involving greater than minimal risk.

Any clinical investigation within the scope described in Secs. 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 and documents that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as set forth in Sec. 50.55.

Sec. 50.52 Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit for the individual subject.

Any clinical investigation within the scope described in Secs. 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 and documents 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
- _____ (c) Adequate provisions are made for soliciting the assent of the children
- _____ Adequate provisions are made for soliciting the permission of their parents or guardians as set forth in Sec. 50.55

VAMHCS Office of Research Compliance**Sec. 50.53 Clinical investigations involving greater than minimal risk and no prospect of direct benefit for the individual subject, but is likely to yield generalizable knowledge about the subjects' disorder or condition.**

Any clinical investigation within the scope described in Secs. 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 and documents 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
- _____ (d) Adequate provisions are made for soliciting the assent of the children
- _____ Adequate provisions are made for soliciting the permission of their parents or guardians as set forth in Sec. 50.55

VAMHCS Office of Research Compliance**Sec. 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 Secs. 50.1 and 56.101 of this chapter and involving children as subjects meets the requirements of Sec. 50.51, Sec. 50.52, or Sec. 50.53, the clinical investigation may proceed only if:

- _____ (a) The IRB finds and documents 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
- _____ (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 Sec. 50.51, Sec. 50.52, or Sec. 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
 - _____ (iii) Adequate provisions are made for soliciting the assent of children
 - _____ Adequate provisions are made for soliciting the permission of their parents or guardians as set forth in Sec. 50.55.

VAMHCS Office of Research Compliance**Sec. 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

_____ This judgment may be made 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

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

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(e) In addition to the determinations required under other applicable sections of this subpart D, the IRB must determine 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, if consistent with State law, for clinical investigations to be conducted under Sec. 50.51 or Sec. 50.52.

_____ (2) Where clinical investigations are covered by Sec. 50.53 or Sec. 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 if consistent with State law.

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

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

Sec. 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 Sec. 50.53 or Sec. 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.