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**SUBJECT:** Waivers and Alterations of Informed  
Consent/Parental Permission

**POLICY:** RA:HRPP:07.04

**DATE EFFECTIVE:**

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**I. POLICY**

The Children's National Medical Center (CNMC) Institutional Review Board (IRB) will grant a waiver or alteration of the consent process and a waiver of the consent document as appropriate. Waivers and alterations will only be approved if the regulatory criteria found in 45 CFR 46.116(c)(d), 46.117(c), 46.408(c) or, for research that is subject to Food and Drug Administration (FDA) regulations, 21 CFR 50.23 or 50.24 are met.

Oral agreement to participate in a research study is NOT permitted unless the documentation or process of informed consent is waived by the IRB.

**II. ACCOUNTABLE EXECUTIVE AND REVIEWER(S)**

- A. Accountable Executive: Chief Academic Officer/Institutional Official for the Federalwide Assurance
- B. Department Responsible for Review: Office for the Protection of Human Subjects
- C. Committee Responsible for Review: Institutional Review Board Executive Committee  
Research Policy/Procedure Working Group

**III. APPROVAL**

Approved by:

\_\_\_\_\_ IRB Executive Committee

\_\_\_\_\_ 11/12/2009  
Date

\_\_\_\_\_ Research Policy/Procedure Working Group

\_\_\_\_\_ Date

\_\_\_\_\_ Mark L. Batshaw, M.D., Chief Academic Officer

\_\_\_\_\_ Date

**IV. APPLICABILITY**

Areas where the policy and procedure applies: Children's Research Institute; Children's National Medical Center

Persons to whom the policy and procedure applies: Institutional Review Board, Office for the Protection of Human Subjects, investigators

**V. REVIEW OR REVISION DATE**

Original:

**VI. REFERENCES**

AAHRPP Element(s):

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR  
46.116(c)(d), 46.117(c), 46.408(c)  
Food and Drug Administration (FDA) 21 CFR 50.23, 50.24



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**PROCEDURE:** RA:HRPP:07.04P

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**I. PROCEDURE**

- A. The Institutional Review Board (IRB) must assure that provisions are made to obtain legally effective informed consent prospectively from each research subject or the subject's legally authorized representative (LAR). In certain circumstances, the regulations allow the IRB to approve waivers or alterations of informed consent. The four types of waivers and alterations that can occur when deemed appropriate by the IRB are:
1. Waiver of documentation of informed consent/parental permission;
  2. Waiver or alteration of some or all elements of informed consent/parental permission;
  3. Exception from the requirement of informed consent under the Emergency Use of a Test Article;
  4. Exception from informed consent requirements for emergency research.
- B. Waiver of Written Documentation of Informed Consent/Parental Permission – 45 CFR 46.117(c)
1. The IRB may approve a consent procedure which waives the requirements for the investigator to obtain a signed consent/parental permission form for some or all subjects, provided the IRB finds and documents the following:
    - a) The research is not regulated by the Food and Drug Administration (FDA).
    - b) The only record that links the subject to the research is the consent document, and potential harm resulting from a breach of confidentiality represents the predominant risk. Each subject will be asked his or her preference as to whether documentation that links him or her to the research is to exist. The subject's preference will prevail.  
or
    - c) The research presents no more than minimal risk of harm to a subject, and involves no procedures for which written consent is normally required outside of the research context.

2. To obtain a waiver of documentation, the investigator is required to complete the Request for Waiver of Documentation of Informed Consent to Participate in a Clinical Research Project form (available on the IRB and Office for the Protection of Human Subjects intranet site) and submit it to the IRB as part of the initial protocol application. The investigator must justify on the form the means by which the waiver criteria b) or c) above are met.
3. The IRB Regulatory Analyst assigned to the study will conduct a pre-review the entire application and make an initial determination whether the study meets criteria for alteration of the requirement to document informed consent. If the Analyst determines that the study does not meet the criteria for a waiver of documentation or additional information is required, he/she will send administrative modifications to the investigator for clarification. Once the administrative modification revisions are received from the investigator, the IRB Regulatory Analyst will forward the protocol documents for review by the appropriate process (expedited or full board review).
4. The assigned reviewer is responsible for conducting a complete review of the application and for confirming the determination that the criteria for waiver of documentation of informed consent are met. An IRB approval stamp is affixed to the Request for Waiver of Documentation form if the investigator's request is approved. The stamped original document is sent to the PI and a copy is retained in the IRB protocol file. If the waiver is approved at a convened IRB meeting, the meeting minutes also must document concurrence or the IRB's determination. If the request is reviewed using the expedited process, the findings of the reviewer will be documented in the protocol record.
5. In cases in which the documentation requirement is waived, the Children's National Medical Center (CNMC) IRB requires the investigator to provide subjects with a written statement (Information Sheet) regarding the research. The investigator must submit the written statement for IRB review and approval before it is used.
  - a) The Information Sheet must be presented to each potential subject in a manner that provides the investigator an opportunity to answer questions, and to either obtain the person's verbal agreement to participate or record their decision to decline participation. The investigator must describe this process in the IRB submission.
6. **NOTE:** The procedure for waiving the requirement for documentation is not intended as a quicker, more convenient method. All required information must still be presented and discussed to ensure a voluntary informed consent process.

C. Waiver or Alteration of Some or All Elements of Informed Consent/Parental Permission

1. For any research that is subject to Department of Health and Human Services (DHHS) regulations, the IRB may approve a consent/permission procedure that does not include or that alters some or all of the elements of informed consent, or that waives the requirements to obtain informed consent, provided that the IRB determines and documents that:

a) The research is not FDA regulated.

**and**

b) **45CFR46.116(c)** -- The research or demonstration project is to be conducted by, or is subject to, the approval of state or local government officials, and is designed to study, evaluate, or otherwise examine:

- i. Public benefit or service programs;
- ii. Procedures for obtaining benefits or services under those programs;
- iii. Possible changes in or alternatives to those programs or procedures; or
- iv. Possible changes in methods or levels of payment for benefits or services under those programs;

and the research could not practicably be carried out without the waiver or alteration; **or**

c) **45CFR46.116(d)**

- i. The research involves no more than minimal risk to the subjects;
- ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- iii. The research could not practicably be carried out without the waiver or alteration; and
- iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

2. Department of Defense-sponsored Research

For Department of Defense-sponsored research, if the research subject meets the definition of “experimental subject,” a waiver of consent is prohibited unless a waiver is obtained from the Secretary of Defense. If the research subject does not meet the definition of “experimental subject,” the IRB may waive consent.

3. Waiver of Parental Permission

a) The IRB may waive the requirement for parental permission for pediatric research (45 CFR 46.116(d)) if the IRB finds:

- i. The research involves no more than minimal risk;
- ii. The waiver or alteration will not adversely affect the rights and welfare of the participants;

- iii. The research could not be practicably carried out without the waiver or alteration;
  - iv. When appropriate, the participants will be provided with additional pertinent information after participation
- b) In addition to the provisions in a) above, the IRB may waive the requirement for parental permission (45 CFR 46.408(c)) if it finds:
- i. The research protocol is designed for conditions or for a participant population for which parent or guardian permission is not a reasonable requirement to protect the participants (e.g., neglected or abused children; or the research involves health care issues subject to confidentiality specific to an adolescent subject);
    - 1) Consult with the CNMC Legal Department regarding informed consent/parental permission if the research involves children who are neglected or abused.
    - 2) Areas of adolescent research that involve sexually transmitted diseases, birth control, and high-risk behaviors and AIDS prevention are common examples of situations in which it may not be in the best interests of the subjects to seek parental permission. Under these circumstances, if the investigator considers it unreasonable to obtain parental permission and would rely solely on the child/adolescent's consent, the IRB is to carefully consider the investigator's request and determine whether the waiver falls within the guidelines established by the Society of Adolescent Medicine (Santelli et al, 2003; accessible at [http://www.adolescenthealth.org/Content/NavigationMenu/Advocacy/PositionPapers/PositionPaper\\_Guidelines\\_for\\_Adolescent\\_Health\\_Research.pdf](http://www.adolescenthealth.org/Content/NavigationMenu/Advocacy/PositionPapers/PositionPaper_Guidelines_for_Adolescent_Health_Research.pdf)) and federal and local regulations.
  - ii. An appropriate mechanism for protecting the children who will participate as participants in the research is substituted; and
  - iii. The waiver is not inconsistent with Federal, State, or local law; investigators should seek advice from the CNMC Legal Department as required to address this issue. The choice of an appropriate mechanism for protecting children would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.
- c) The FDA has not adopted the section of the federal regulations (45 CFR 46.408(c)) that allow for waiver of parental permission. Therefore, protocols that involve children that are subject to FDA regulations may not waive the requirement for obtaining parental permission under these criteria.

4. To obtain a waiver or alteration of informed consent, the investigator is required to complete the Request for Waiver of Consent to Participate in a Clinical Research Project form (available on the IRB and Office for the Protection of Human Subjects intranet site) and submit it to the IRB as part of the initial protocol application. The investigator must provide sufficient justification of the means by which the waiver/alteration criteria are met.
5. The IRB Regulatory Analyst assigned to the study will conduct a pre-review the entire application and make an initial determination whether the study meets criteria for a waiver or alteration of some or all of the elements of informed consent. If the Analyst determines that the study does not meet the criteria for a waiver/alteration of informed consent or if additional information is required, he/she will send administrative modifications to the investigator for clarification. Once the administrative modification revisions are received from the investigator, the IRB Analyst will forward the protocol documents for review by the appropriate process (expedited or full board review).
6. The assigned reviewer is responsible for conducting a complete review of the application and for confirming the determination that the criteria for waiver/alteration of informed consent are met. An IRB approval stamp is affixed to the Request for Waiver of Documentation form if the investigator's request is approved. The stamped original document is sent to the PI and a copy is retained in the IRB protocol file. If the waiver/alteration is approved at a convened IRB meeting, the meeting minutes also must document concurrence or the IRB's determination. If the request is reviewed using the expedited process, the findings of the reviewer will be documented in the protocol record.

D. Exception from the Requirement of Informed Consent under the Emergency Use of a Test Article – 21 CFR 50.23

1. It may not be feasible to obtain informed consent from a subject or his/her legally authorized representative in a life-threatening situation where standard treatment is unavailable and treatment with an investigational product or procedure is thought to be in the best interest of the subject. FDA regulations allow such emergency use of a test article for one patient only without prior informed consent if the investigator and a physician who is not otherwise participating in the clinical investigation certify, in writing, all of the following:
  - a) The subject is confronted by a life-threatening situation necessitating the use of the test article.
  - b) Informed consent cannot be obtained from the subject because of an inability to communicate with or obtain legally effective consent from the subject, if over the age of 18, or from the parent/guardian if the subject is under age 18.
  - c) Time is not sufficient to obtain consent from the subject's legal representative.

- d) No alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject is available.

2. For information on IRB submission requirements for emergency use of a test article, see RA:HRPP:05.13 and 05.13P, *Emergency Use Exemption from Prospective IRB Approval*.

E. Exception from Informed Consent Requirements for Emergency Research – 21 CFR 50.24

Researchers who plan to conduct research protocols in an emergency setting, when they know that it will not be possible to obtain consent from the patient or legally authorized representative and the research involves an FDA-regulated product, are required to conduct the research in accordance with the FDA regulations 21 CFR 50.24. Planned emergency research where an exception from informed consent is being requested is addressed in RA:HRPP:09.10 and 09.10P, *Exception from Informed Consent Requirements for Emergency Research Protocols*. Researchers should consult with the Office for the Protection of Human Subjects and the IRB Chair in preparing their applications for emergency research.

F. Emergency Research Involving Non-FDA Regulated Products

When the IRB finds and documents that the emergency research is not subject to regulations codified by the FDA at title 21 CFR part 50, the following must also apply:

1. The IRB finds and documents that:
  - a) The research participants are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
  - b) Obtaining consent is not feasible because:
    - i. The participants are not able to give their consent as a result of their medical condition.
    - ii. The intervention involved in the research is administered before consent from the participants' legally authorized representatives is feasible.
    - iii. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.
2. Participation in the research holds out the prospect of direct benefit to the participants because:

- a) Participants are facing a life-threatening situation that necessitated intervention.
  - b) Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence supports the potential for the intervention to provide a direct benefit to the individual participants.
  - c) The risks associated with the research are reasonable in relation to what is known about the medical condition of the potential class of participants, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
3. The research cannot practicably be carried out without the waiver.
  4. The proposed research protocol defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each participant within that window of time and, if feasible, asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact representatives and make this information available to the IRB at the time of continuing review.
  5. The IRB has reviewed and approved consent procedures and a consent document in accord with 45 CFR 46.116 and 46.117.
    - a) These procedures and the consent document are to be used with participants or their legally authorized representatives in situations where use of such procedures and documented is feasible.
    - b) The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a participant's participation in the research consistent with the paragraph of this waiver.
  6. Additional protections of the rights and welfare of the participants are provided, including, at least:
    - a) Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research is conducted and from which the participants are drawn.
    - b) Public disclosure to the communities in which the research is conducted and from which the participants are drawn, prior to initiation of the research, of plans for the research and its risks and expected benefits.
    - c) Public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results.

- d) Establishment of an independent data monitoring committee to exercise oversight of the research.
- e) If obtaining consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the participant's family member who is not a legally authorized representative, and asking whether he or she objects to the participant's participation in the research.
  - i. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.
  - ii. Procedures are in place to inform, at the earliest feasible opportunity, each participant, or if the participant remained incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, of the participant's inclusion in the research, the details of the research and other information contained in the consent document.
  - iii. There is a procedure to inform the participant, or if the participant remained incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, that he or she may discontinue the participant's participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
  - iv. If a legally authorized representative or family member is told about the research and the participant's condition improves, the participant is also informed as soon as feasible.
  - v. If a participant is entered into research with waived consent and the participant dies before a legally authorized representative or family member can be contacted, information about the research is provided to the participant's legally authorized representative or family member, if feasible.
  - vi. For the purposes of this waiver "family member" means any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the participant is the equivalent of a family relationship.

#### G. Deferred Consent or Ratification of Informed Consent

Informed consent procedures which provide for other than legally authorized and prospectively obtained consent fail to constitute informed consent under Federal regulations for the protection of human participants in research. Therefore, waiving informed consent using a method other than those described in this policy is a violation of Human Research Protections Program and CNMC IRB policies

and procedures and Federal regulations and is subject to reporting to the appropriate Federal, State, and Institutional officials.

## II. REVIEW OR REVISION DATE

Original:

## III. REFERENCES

AAHRPP Element(s):

Federal Regulations: Food and Drug Administration (FDA) 21 CFR 50.23, 50.24  
U.S. Department of Health and Human Services (DHHS) 45 CFR  
46.116(c)(d), 46.117(c), 46.408(c)

Santelli JS, Smith Rogers A, Rosenfeld WD, DuRant RH, Dubler N, Morreale M, English A, Lyss S, Wimberly Y, Schissel A; Society for Adolescent Medicine. Guidelines for adolescent health research: A position paper of the Society for Adolescent Medicine. *J Adolesc Health*. 2003 Nov; 33(5):396-409. Accessed April 21, 2010 at

[http://www.adolescenthealth.org/Content/NavigationMenu/Advocacy/PositionPapers/PositionPaper\\_Guidelines\\_for\\_Adolescent\\_Health\\_Research.pdf](http://www.adolescenthealth.org/Content/NavigationMenu/Advocacy/PositionPapers/PositionPaper_Guidelines_for_Adolescent_Health_Research.pdf)

Policies and procedures: RA:HRPP:05.13 and 05.13P, *Emergency Use Exception from Prospective Institutional Review Board Approval*

RA:HRPP:09.10 and 09.10P, *Exception from Informed Consent Requirements for Emergency Research Protocols*

Forms: Request for Waiver of Consent

Request for Waiver of Documentation of Informed Consent to Participate in a Clinical Research Project