SUBJECT: Obtaining Informed Consent/Parental Permission and Assent via Telephone and Mail

POLICY: RA:HRPP:07.05

DATE EFFECTIVE:

I. POLICY

Children's National Medical Center (CNMC) Institutional Review Board (IRB) policy and federal regulations state that informed consent must be obtained prior to obtaining any study information, and that the entire consent process should be accurately documented. (45 CFR 46.116, 46.117; 21 CFR 50.25, 50.27)

The research design of certain studies (e.g., telephone surveys) may entail a process for obtaining informed consent/assent by telephone and through the mail, with the justification that this method is appropriate when face-to-face contact with subjects and parents/guardians is neither necessary for the study nor practicable. When determining if telephone and mail consent/assent is appropriate, the CNMC IRB takes into consideration the rights and welfare of potential subjects under these circumstances.

The current policy applies to protocols for which consent/assent by telephone and mail is planned and included as part of the study design.

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 and research staff

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, 46.117
Food and Drug Administration (FDA) 21 CFR 50.25, 50.27

SUBJECT: Obtaining Informed Consent/Parental Permission and Assent via Telephone and Mail

PROCEDURE: RA:HRPP:07.05P

DATE EFFECTIVE:

I. PROCEDURE

A. This procedure describes the recommended method for obtaining informed consent and assent over the telephone and through the mail. This section applies to protocols for which consent/assent by telephone and mail is planned and included as part of the study design. For studies designed to obtain consent/parental permission in person, refer to RA:HRPP:07.03 and 07.03P, *Documentation of Informed Consent/Parental Permission and Assent*, for guidelines on obtaining consent/parental permission if the parent/guardian is not present to sign the informed consent document within a timeframe specified by the research protocol.

B. "Cold calling" is not an acceptable recruitment practice. Potential subjects may not be contacted for recruitment by telephone without prior notification, such as a letter, that enables them to decline further contact.

C. As with any human subjects research, the investigator must provide subjects and/or their parent(s) or legally authorized representative with the basic elements of informed consent during the consenting process and in all informed consent/parental permission documents (RA:HRPP:07.01 and 07.01P, *Elements of Informed Consent*), unless waived by the Institutional Review Board (IRB). Additional elements should be included as appropriate. (45 CFR 46.116, 46.117; 21 CFR 50.25, 50.27)

D. The IRB must approve the informed consent process and method of documentation prior to study implementation, indicating whether the proposed consent process is appropriate for the proposed research activities and the target population as a part of the overall IRB approval of the study. The investigator must provide a detailed description of the consent process (RA:HRPP:07.02 and 07.02P, *Informed Consent/Parental Permission and Assent Process*) and documentation procedures in the IRB protocol application submission.

1. Prior to submission to the IRB, letters and any other recruitment materials to be sent to potential subjects must be reviewed and approved by the Public Relations (PR) and Marketing Department.

2. The investigator must submit the recruitment documents approved by PR and Marketing, as well as all consent/assent forms and telephone scripts for the consenting process, to the Institutional Review Board (IRB) for approval.

E. When obtaining informed consent/parental permission and assent via telephone and through the mail, investigators are advised to do the following:

1. Mail two copies of the informed consent/parental permission form for *each* subject and for *each* parent/guardian of *each* participating child or adolescent. Include instructions to call the Principal Investigator (PI) or a member of the research staff when consents are received. Include the appropriate number of self-addressed, stamped envelopes (SASEs) for the convenience of the subject and/or parent(s)/guardian.

2. Once each subject and parent/guardian has a copy of the consent or assent form in front of them, the PI or research staff member must review the study and consent document over the phone <u>with each subject and parent/guardian</u>, asking questions to gauge comprehension, and answering their questions and concerns. The PI/staff member should document the entire informed consent/assent process for each person in a memo or related study document.
    a) It may be necessary to have more than one telephone conversation with the subject and parent/guardian. Individuals must be given sufficient time to consider whether they want (their child) to participate in the study.

3. After all questions are answered and the PI/research staff member feels confident that each subject and parent/guardian understands the study, have each person sign and date consent/permission form (recommended to flag or highlight the correct signature line), and mail back the signed consent copy in the SASE(s) provided. Each signatory should keep the other copy of the consent for their files.

4. <u>If assent is required, you must also speak with the child or adolescent directly</u> to explain the study and ask questions to gauge comprehension. This must be done in addition to obtaining parental permission.

5. To document assent, ensure that the child or adolescent signs and dates the subject/participant line of the appropriate assent form.

F. Investigator Documentation

1. Once the signed forms are received by the study team, *the PI/research staff member that explained the study should sign the appropriate signature line with current date (not the date they spoke with subject or parent/guardian).* The PI/staff member signatory should specify to whom the study was explained within the PI/PI authorized signatory section.

2. Only after a subject or parent/guardian signs the consent/assent form is the individual who obtained consent to sign the document. The signature of the person who obtains consent is not to be 'back dated' to coincide with the date of the research subject's signature (RA:HRPP:07.03P).

3. The PI/staff member should ensure that all signatures and dates were accurately documented. Any errors should be noted in a note or memo. If necessary, re-consent the subject and parent/guardian.

4. It is recommended to document in a note under the PI signature line that consent was obtained over the telephone with actual date and mailed back. E.g. "*Discussed with [person] via telephone on [insert date], and received signed consent form on [insert date].*"

G. Investigators and research staff are reminded that consent is an on-going process throughout the subject's involvement in the research. They are to respond appropriately to questions, complaints, or requests for information from subjects before, during, and after the subject's participation.

II. REVIEW OR REVISION DATE

Original:

III. REFERENCES

AAHRPP Elements:

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.116, 46.117
Food and Drug Administration (FDA) 21 CFR 50.25, 50.27

Policies and Procedures: RA:HRPP:07.01 and 07.01P, *Elements of Informed Consent*
RA:HRPP:07.02 and 07.02P, *Informed Consent/Parental Permission and Assent Process*
RA:HRPP:07.03 and 07.03P, *Documentation of Informed Consent/Parental Permission and Assent*