



## POLICY ON USE OF QUESTIONNAIRES BY TELEPHONE OR MAIL

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**Introduction.** The administration of questionnaires by telephone or by mail for research purposes requires IRB exemption or approval according to federal regulations. The IRB policy outlined below provides guidelines that differ according to whether the questionnaire is for ascertainment of subjects or for data to be used in the research, whether the questionnaire is administered verbally by telephone or in writing by mail, and whether the consent and authorization (C/A) is verbal, written, or implied.

**A. SCREENING QUESTIONNAIRES FOR ASCERTAINMENT OF SUBJECTS.** Screening questionnaires for ascertainment of subjects may be administered to potential subjects by either telephone or mail. For both methods it usually is necessary to obtain C/A or waiver of C/A before the questionnaire is administered.

**1. Verbal screening by telephone.** Screening questionnaires can be administered by telephone. Sometimes the screening is done by calling potential subjects who have been identified from medical record data following IRB approval (Waiver of Consent and Authorization), or who have responded positively by mail to IRB approved advertisements. Sometimes screening is done by answering calls from potential subjects who are responding by telephone to advertisements.

**a. Possible exemption.** Exemption of initial telephone screening from IRB review under the Common Rule may be considered under 45CFR46.101(b)(2) in the special case when study eligibility is being determined without recording any individual private information or protected health information (PHI). This is possible only when interested persons call in to ask about the study and to see if they might be eligible. The interviewer would describe the study, answer questions, and determine eligibility without recording any information other than the name and contact information of the callers and their eligibility status. After the eligibility screening call, any contact with the potential subjects for administering questionnaires with recorded PHI and for obtaining C/A would require adherence to the relevant guidelines outlined below.

**b. Verbal C/A for verbal screening.**

(1) **Telephone script.** When protected health information (PHI) is recorded during the telephone screening process, the potential subjects must be informed about the research study, and their verbal C/A must be obtained before any questions are asked. The interviewer must use an IRB approved telephone script that contains at a minimum the following elements of C/A that the DUHS IRB has determined to be relevant for screening:

- (a) Purpose of the telephone call,
- (b) Brief description of the research that includes the purposes, duration, procedures to be followed, and which procedures are experimental,
- (c) Who will use the screening information and for how long, and
- (d) How privacy and confidentiality will be assured.

(See Attachment 1 for the full list of basic elements of C/A.)

(2) **Waivers.** Because verbal instead of written C/A is being obtained, the Common Rule requires a Waiver of Documentation (See Attachment 2 for criteria.), and the Privacy Rule (HIPAA) requires a Waiver or Alteration of Authorization. (See Attachment 3 for criteria.) The forms for requesting these waivers are available on the IRB website <http://irb.mc.duke.edu>.

**c. Written C/A for verbal screening.**

(1) Telephone script. If waiver or alteration of verbal C/A is not justified, or if written C/A is preferred for administering the screening questionnaire by telephone, written C/A must be obtained by mail. Potential subjects must be informed in the initial telephone interaction, using an IRB-approved script, that a C/A form will be mailed to them, and that they will be called to answer questions before they sign the form. After the signed C/A form is received by the PI, the subject will be called for administration of the telephone screening questionnaire. (See Attachment 4 for the procedure for obtaining C/A by mail.)

(2) C/A form. The C/A form for permission to administer the telephone screening questionnaire must contain at a minimum the basic elements of C/A that are listed in Section A1b(1) above. Also, there must be a signature line for a witness to verify the subject's signature.

**d. Implied C/A for verbal screening.** (Not applicable)

**2. Written screening by mail.** If written screening questionnaires are preferred, they can be mailed to potential subjects for completion. Sometimes the questionnaires are mailed to potential subjects who have been identified from medical record data following IRB notification (HIPAA Review Preparatory to Research) or IRB approval (HIPAA Waiver of Authorization), or who have responded positively by telephone or mail to IRB-approved advertisements.

**a. Verbal C/A for screening by mail.** Potential subjects can be consented verbally for completing a written screening questionnaire that will be mailed to them. The same procedure should be followed as that described for verbal C/A for verbal screening in Section A1b above.

**b. Written C/A for screening by mail.** Potential subjects also can be consented by a C/A form that is sent by mail along with the screening questionnaire.

(1) Cover letter. The cover letter should explain the study and the C/A form, and inform the potential subjects that they will be called in about two weeks to answer questions. (See Attachment 4 for the procedure for obtaining C/A by mail.)

(2) C/A form. The C/A form for the screening questionnaire must contain at a minimum the basic elements of C/A that are listed in Section A1b(1) above. Also, there must be a signature line for a witness to verify the subject's signature.

**c. Implied C/A for screening by mail.** The IRB may consider approval of implied C/A for mailed screening questionnaires.

(1) Cover letter. When the questionnaire is mailed, it must be accompanied by an IRB-approved cover letter that informs potential subjects about the research study. The letter must contain the relevant basic elements of C/A that are outlined in Section A1b(1) above. Then C/A is implied, if and when potential subjects complete and return the questionnaire.

(2) Waivers. Because written C/A is not being obtained, the Common Rule requires a Waiver of Documentation (See Attachment 2 for criteria.), and the Privacy Rule (HIPAA) requires a Waiver or Alteration of Authorization. (See Attachment 3 for criteria.) The forms for requesting these waivers are available on the IRB website <http://irb.mc.duke.edu>.

**B. QUESTIONNAIRES FOR COLLECTION OF RESEARCH DATA.** Questionnaires that collect data to be used in a research study may be administered to subjects by telephone or mail. C/A for participation in the research study and for completing the questionnaires must be obtained or waived before the questionnaires are administered by either telephone or mail.

**1. Verbal collection of research data by telephone.** When the questionnaires are to be administered by telephone, it is necessary to obtain C/A if it has not been obtained in the past and to obtain a waiver or alteration of C/A when required.

**a. Written C/A for verbal collection of research data.** The preferred method for obtaining C/A for telephone research questionnaires is by including C/A in the original written C/A form for the

research study. If this has been done before the telephone call, then the telephone script needs only to describe the questionnaire and remind subjects that they agreed to participate in the study and to be called to answer questions.

If the original C/A did not include permission for a telephone questionnaire, the IRB must approve an amendment to the original study protocol that includes the questionnaire and a C/A addendum form. When mail is used to obtain signatures on the C/A addendum, the procedure in Attachment 4 should be followed.

**b. Verbal C/A for verbal collection of research data.** The IRB may consider approval of verbal C/A for a research questionnaire administered by telephone. Again, if the original C/A did not include the questionnaire, an amendment and C/A addendum will be needed.

(1) Telephone script. The script must contain all of the basic elements described in Attachment 1.

(2) Waivers. Because verbal instead of written C/A is being obtained, the Common Rule requires a Waiver of Documentation (See Attachment 2 for criteria.), and the Privacy Rule (HIPAA) requires a Waiver or Alteration of Authorization. (See Attachment 3 for criteria.) The forms for requesting these waivers are available on the IRB website <http://irb.mc.duke.edu>.

**c. Implied C/A for verbal collection of research data.** (Not applicable.)

**2. Collection of written research data by mail.** When the questionnaires are to be administered by mail, it is necessary to obtain C/A if it has not been obtained in the past and to obtain a waiver or alteration of C/A when required.

**a. Written C/A for collection of written research data by mail.** The preferred method for obtaining C/A for mailed research questionnaires is by including it in the original C/A form for the research study. If this has been done, then the cover letter to the subjects needs only to describe the questionnaire and remind subjects that they agreed to participate in the study and to respond to a mailed questionnaire.

If the original C/A did not include permission for a mailed questionnaire, the IRB must approve an amendment to the original study protocol that includes the questionnaire and a C/A addendum form. When mail is used to obtain signatures on the C/A addendum, the procedure in Attachment 4 should be followed.

**b. Verbal C/A for collection of written research data by mail.** The IRB may consider approval of verbal C/A for mailed research data questionnaires. The procedure should be the same as for verbal questionnaires described in Section B1b above.

**c. Implied C/A for collection of written research data by mail.** Implied consent may be considered by the IRB to be satisfactory for certain studies in which the information requested by the mailed questionnaire is of such low potential risk to the subject that written or verbal C/A would be unnecessary.

(1) Cover letter. When the questionnaire is mailed, it must be accompanied by an IRB-approved cover letter that informs potential subjects about the research study. The letter must contain all of the basic elements of C/A described in Attachment 1. Then C/A is implied, if and when potential subjects complete and return the questionnaire.

(2) Waivers. Because written C/A is not being obtained, the Common Rule requires a Waiver of Documentation (See Attachment 2 for criteria.), and the Privacy Rule (HIPAA) requires a Waiver or Alteration of Authorization. (See Attachment 3 for criteria.) The forms for requesting these waivers are available on the IRB website <http://irb.mc.duke.edu>.

## ATTACHMENT 1: Basic Elements of Consent and Authorization

### COMMON RULE BASIC ELEMENTS OF CONSENT [Excerpts quoted from 45CFR46.116(a)]

- “(a) ...statement that the study involves research...purposes of the research...expected duration...procedures to be followed...and identification of any procedures which are experimental,
- (b)...risks or discomforts,
- (c) ...benefits,
- (d)...alternative procedures or...treatment, [Not applicable for minimum risk studies.]
- (e)...extent to which...confidentiality of records...will be maintained,
- (f)...compensation...and... available medical treatments if injury occurs, [Not applicable for minimum risk studies.]
- (g)...whom to contact...for questions about the research and research subject’ rights,
- (h)...participation is voluntary...refusal...will involve no penalty...and the subject may discontinue participation at any time.”

### PRIVACY RULE (HIPAA) CORE ELEMENTS AND REQUIRED STATEMENTS FOR USE OR DISCLOSURE OF PHI [Excerpts quoted from 45CFR164.508(c)]

- “(a) Core Elements...
  - i ...information to be used or disclosed,
  - ii ...identification of the person(s)...authorized to make the requested use or disclosure,
  - iii...identification of the person(s)...to whom [DUHS] may make the requested use or disclosure,
  - iv...each purpose of the requested use or disclosure,
  - v...an expiration date...of the use or disclosure,
  - vi...signature of the individual and date.
- (b) Required Statements...
  - i...individual’s right to revoke the authorization in writing,
  - ii...condition treatment...on the authorization,
  - iii...potential for information...to be subject to redisclosure...and no longer protected.
- (c) Plain Language Requirement...
- (d) Copy to the Individual...”

## ATTACHMENT 2: Requirements for Waiver of Documentation of Consent

### COMMON RULE WAIVER OF DOCUMENTATION OF CONSENT [45CFR46.117(c)]

- “(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. .; or
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.”

### **ATTACHMENT 3: Requirements for Waiver of Consent and Authorization**

#### **COMMON RULE WAIVER OF CONSENT [45CFR46.116(d)]**

“An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.”

#### **PRIVACY RULE (HIPAA) WAIVER OF AUTHORIZATION [45CFR164.512(i)(2)(ii)]**

“Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

- (A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
  - (1) An adequate plan to protect the identifiers from improper use and disclosure;
  - (2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - (3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of protected health information would be permitted by this subpart;
- (B) The research could not practicably be conducted without the waiver or alteration; and
- (C) The research could not practicably be conducted without access to and use of the protected health information.”

### **ATTACHMENT 4: Procedure for Obtaining Consent and Authorization (C/A) by Mail**

1. Contact potential subjects to explain the study and the C/A process. When contact is made by telephone, an IRB-approved script must be used to explain the study and to inform potential subjects that a C/A will be mailed to them, after which they will be called in about two weeks to answer their questions. When contact is made by mail, an IRB-approved cover letter must be used to explain the study and give instructions. The C/A form can be included in the mailing;
2. The cover letter for the mailed C/A form must include instructions that cover the following:
  - a. Read the form carefully.
  - b. Before signing the form, wait until after the researcher calls to answer questions.
  - c. Sign the form if willing to participate in the study.
  - d. Have another adult sign the form as a witness.
  - e. Send the signed form back to the researcher by mail or fax;
3. Wait until the signed C/A form has been received by the investigator before using PHI from the questionnaire for research purposes; and

4. Mail to the subject a copy of the C/A form that has all the required signatures, i.e., those of the subject, the witness, and the person obtaining C/A.