SUBJECT CONSENT and RELEASE PROTOCOL

I. Introduction

The purpose/goal of the Consent forms is to provide accurate and relevant information about the study and its purpose; disclosing known risks, benefits and alternatives, and procedure answering questions; and enabling the potential participant to make an informed decision whether to participate or not. The Medical Records and Tissue Release Forms

II. Procedures

A. Administration

The PCaP Consent Forms and Releases will be administered to all study participants by a trained and certified study nurse conducted as part of the in-home visit. These will be administered after Background Characteristics demographic confirmation and before the Background Questionnaire. Institutionally specific documents for LSU and UNC-CH will be reviewed and signed by the potential participant prior to proceeding with the study questionnaires and specimen collection.

B. Materials Needed

Forms:

LSUHSC

1. Louisiana State University Health Sciences Center In New Orleans *Consent Form*
2. Louisiana State University Health Sciences Center In New Orleans Institutional Review Board *Authorization For Use and Disclosure of Protected Health Information for Research Purposes*
3. Louisiana State University Health Sciences Center In New Orleans *Medical Records Cover Letter and Release Form*
4. Louisiana State University Health Sciences Center In New Orleans *Request for Release of Tissue Specimens*

UNC

1. PCaP UNC- Chapel Hill *Consent to Participate in a Research Study, Literate*
2. PCaP UNC- Chapel Hill *Consent to Participate in a Research Study, Illiterate*
3. PCaP UNC-Chapel Hill *Addendum to Consent Form For Participating in a Research Study* (HIPAA Authorization for use of Protected Health Information)
4. PCaP UNC-Chapel Hill *Request for Release of Medical Records*
5. PCaP UNC-Chapel Hill *Request for Release of Tissue Specimens*

Other:

1. Gel Pen—Black Ink only-Medium Thickness

C. Instructions to the Study Nurse

Informed consent, as a legal, regulatory and ethical concept is a process conveying accurate and relevant information about the study and its purpose; disclosing known risks, benefits and alternatives, and procedure answering questions; and enabling the potential participant to make an informed decision whether to participate or not. The individual may refuse to participate in part or all of the study.

D. General Introduction

Informed Consent - Protection of Human Subjects

Introduction

No clinical investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent from the subject. Informed Consent is a written notification to human subjects involved in clinical investigations that provides them with sufficient opportunity to consider whether or not to participate in the study. The informed consent document must include all the basic elements of informed consent (outlined below) or it may be a short form written consent document stating that the elements of informed consent have been presented orally (§50.27). If the short form method is used, there must be a witness to the oral presentation.

An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. 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, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

The written consent form must be approved by the Institutional Review Board (IRB) and contain the following basic elements (§50.25):

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and 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 and 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 and an explanation as to whether any medical treatments are available if injury occurs and, 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 and research subjects' rights, and who to contact in the event of a research related injury to the subject.

8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

9. Additional elements of informed consent. When appropriate, one or more of the following elements of information must be provided to each subject:
    a. A statement that a 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.
    b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
    c. Any additional costs to the subject that may result from participation in the research.
    d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
    e. 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.
    f. The approximate number of subject's involved in the study.

The consent form must be signed by the subject or the subject's legally authorized representative. Each signed consent must be maintained by the clinical investigator and a copy of the informed consent must be provided to the human subject.

(from FDA –see references)

HIPAA - PRIVACY RULE AS IT RELATES TO RESEARCH

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION [45 CFR Parts 160 and 164] *or* (HIPAA PRIVACY RULE)

RESEARCH [*45 CFR 164.501, 164.508, 164.512(i)*] [See also *45 CFR 164.514(e), 164.528, 164.532*]

What is the HIPAA Privacy Rule?

The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities. (Because the Health Sciences Center is involved in health care delivery it is a covered entity) By the compliance date of April 14, 2003, covered entities must implement standards to protect and guard against the misuse of individually identifiable health information. These standards apply to human subjects research.

Is this in addition to IRB oversight under the Common Rule?

Yes, although there is considerable overlap in the protection provided subjects under the two programs, the Privacy Rule establishes a second mandated, compliance program, in part, directed at protecting individuals volunteering to participate in research. The Common Rule specifically protects the welfare of subjects. The Privacy Rule expands on this concept and specifically protects the use and disclosure of certain health information. An additional important difference between the two Rules is that, failure to implement and comply with the Privacy Rule standards may, under certain circumstances, trigger the imposition of civil or criminal penalties.

How does the Rule work with regard to research?

In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule. More detailed explanations of the Privacy Rule and how the Privacy Rule relates to research can be seen at the following web sites:

Office of Civil Rights Guidance on the Privacy Rule:

- http://www.hhs.gov/ocr/hippa/privacy.html
- http://www.hhs.gov/ocr/hipaa/guidelines/research.pdf

Information considered identifiers under the HIPAA Privacy Rule:

The pieces of information considered identifiers under the Privacy Rule include the following items:

- Names

- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
    - The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
    - The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code;

And, the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information. (from LSUHSC – see references)

DEFINITIONS:

Accounting of Disclosures- A research subject has the right to receive a written accounting of certain research disclosures of his/her PHI to individuals or entities outside of the LSU System and UNC health care components.

Authorization - A written document completed and signed by the individual that allows use and disclosure of PHI for specified purposes other than treatment, payment or health care operations.

Common Rule – The Federal Policy for the Protection of Human Subjects that is currently in effect, as described in 45 CFR part 46(A). The Common Rule provides protections for individuals and establishes the role of Institutional Review Boards (IRB) in achieving those protections.

De-identified Information – Health information that does not identify an individual and data from which there is no reasonable basis to believe that the information can be used to identify an individual. All identifiers have been removed pursuant to federal Privacy Rule § 164.514 (b) (2). De-identified information is not considered protected health information. (from FDA – see references)

Dialogue for the Study Nurse:

Dialog for the LSU and UNC nurses will have variances: the UNC Consent Forms will be mailed to the potential participant with the interview appointment confirmation letter to be read prior to the visit. The LSU Consent Forms will be presented to the potential participant during the initial phase of the visit and be read to the potential participant to insure complete understanding prior to signature and consent.

TRAINING for ADMINISTRATION OF CONSENTS AND RELEASE FORMS

I. Participants

All study nurses (trainees) who will be certified as administrators at each site must participate in certification training.

II. Date and Time Required

All site training sessions are to be scheduled in advance of the administration of the Consent and Release Forms as part of the in-home visit. Allow adequate time for each administrator to complete all certification requirements**.**

III. Preparation

A. Materials

LSUHSC

2. Louisiana State University Health Sciences Center In New Orleans *Consent Form*
3. Louisiana State University Health Sciences Center In New Orleans Institutional Review Board *Authorization For Use and Disclosure of Protected Health Information for Research Purposes*
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B. Prior Preparation by trainees

1. Read over General Study Consent and Release Forms Protocol

2. Read over the Procedures for Certification

IV. Training

A. Mock Administration of Consents and Release Forms
B. Review administration of protocol
    1. Introduction
    2. Procedures
        a. Administration
        b. Materials
        c. Instructions to Study Nurse
        d. Introduction to Consent and Release Forms
C. Mock completion of all forms.

V. Review Procedures for Certification

VI. QxQ and Update

A. Question: In the case of an illiterate subject, as long as a 3rd party is present, can the UNC nurse read the full consent to the research subject rather than asking the 3rd party to read it?

Answer: Yes. As of May 15th (amendment # 2), UNC nurse will read full consent form and full release forms to an illiterate subject with a 3rd party witness present.

B. Does the research subject have to check the boxes on the consent form for specimen collection/ use or can the nurse do it for them?

Answer: The study subject must check the boxes.

References:

FDA Informed Consent - Protection of Human Subjects
NIH-FDA Self Tutorial on Human Subjects Protection
The Belmont Report
LSUHSC Policies and Procedures for Research

ADDENDUM I (2/7/06)

Consenting Literate PCaP subjects in NC

To summarize the signatures for consenting **literate** PCaP subjects in NC:

1. The subject signs where indicated for him on the
    a. Literate consent form
        i. individual section checkboxes (such as for the interviews, the blood draw, etc.)
            1. checkmarks or initials signed by the subject are acceptable in these fields
        ii. page 10
    b. HIPAA authorization form
    c. Medical records, biopsy tissue, and prostatectomy tissue releases as applicable

2. The nurse, as the "person obtaining consent," signs where indicated on the
    a. Literate consent form
        i. page 10
        ii. HIPAA authorization form

Consenting Illiterate PCaP subjects in NC

Consenting **illiterate** PCaP subjects in NC requires:

1. the presence of a witness.
    a. If a witness is not available at the visit site, the NC nurse may call Jeannette, Diane, Liz, or another PCaP nurse to serve as a witness by phone.
        i. In this case, the subject must acknowledge his presence in the room (such that the phone witness can attest to his presence).

2. the use of the illiterate consent form.
    a. The illiterate consent form includes the same text as the literate consent form. However, the illiterate version differs in two ways:
        i. It has a cover sheet (p.1 of 11) containing "Documentation of verbal presentation of English language consent form" and signature lines for all three parties: illiterate subject, person obtaining consent (i.e., nurse), and witness.
        ii. The signatures on the last page (p.11) of the illiterate consent should be from the person obtaining consent (i.e., nurse) and the witness. (On the literate version, the person obtaining consent and the subject sign the last page.)

3. that the nurse read aloud the entire consent packet to the illiterate subject, with the witness following along on the forms.
    a. This reading by the nurse includes the illiterate consent form, the HIPAA authorization form, and the release forms (medical records, biopsy tissue, and prostatectomy tissue, where applicable).

To summarize the signatures for consenting **illiterate** PCaP subjects in NC:

1. The subject signs where indicated for him on the
    a. Illiterate consent form
        i. page 1
        ii. individual section checkboxes (such as for the interviews, the blood draw, etc.)
            1. checkmarks or initials signed by the subject are acceptable in these fields
    b. HIPAA authorization form
    c. Medical records, biopsy tissue, and prostatectomy tissue releases as applicable

2. The witness signs where specifically indicated on the illiterate consent form (p.1, p.11).

3. The nurse, as the "person obtaining consent," signs where indicated on the
    a. Illiterate consent form
        i. page 1
        ii. page 11
    b. HIPAA authorization form

For subjects who are unexpectedly found to be illiterate, as determined at the time of the visit:

1. Nurses are responsible for keeping blank copies of the currently approved, eleven-page illiterate consent form in their study visit supplies.

2. The nurse will then exchange the entire 11-page illiterate consent form for the entire 10-page literate consent form.
    a. The copies of the unused literate consent form must be shredded.
    b. The HIPAA authorization form and the three release forms remain the same.