

November 9, 1995

TO: Professional Staff
Division of Human Subject Protections, OPRR

FROM: Director
Division of Human Subject Protections, OPRR

SUBJECT: OBTAINING AND DOCUMENTING INFORMED CONSENT OF
SUBJECTS WHO DO NOT SPEAK ENGLISH

Department of Health and Human Services regulations for the protection of human subjects require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing ([45 CFR §46.116](#) and [§46.117](#)).

Where informed consent is documented in accordance with [§46.117\(b\)\(1\)](#), the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them. OPRR strongly encourages the use of this procedure whenever possible.

Alternatively, [§46.117\(b\)\(2\)](#) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written document (see sample attached) should be in a language understandable to the subject; (ii) the IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject.

At the time of consent, (i) the short form document should be signed by the subject (or the subject's legally authorized representative); (ii) the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and (iii) the short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

The IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of [§46.117\(b\)\(2\)](#). Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

It is the responsibility of the IRB to determine which of the procedures at [§46.117\(b\)](#) is appropriate for documenting informed consent in protocols that it reviews.

Melody H. Lin, Ph.D.

Attachment: Sample Short Form Consent Document For Subjects Who Do Not Speak English

cc: Gary B. Ellis, Ph.D.

SAMPLE SHORT FORM WRITTEN CONSENT DOCUMENT
FOR SUBJECTS WHO DO NOT SPEAK ENGLISH
***THIS DOCUMENT MUST BE WRITTEN IN A LANGUAGE UNDERSTANDABLE
TO THE SUBJECT***

Consent to Participate in Research

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact name at phone number any time you have questions about the research.

You may contact name at phone number if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

signature of participant	date
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signature of witness	date
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11/09/95