required and must be obtained prior to use. In addition, continuing research that is federally funded and is conducting research with newborn dried blood spots collected on or after March 18, 2015, will also have to comply with these new requirements. Non-identifiable newborn dried blood spots collected prior to March 18, 2015, may continue to be used in federally funded research without parental permission, and this activity would continue to be considered research that does not involve human subjects under the current human subjects regulations. The NIH recognizes that there is no universal agreement on the optimal timing for collection of parental permission for research purposes. Obtaining permission at the time the dried blood spots are collected may be one option. Ideally, an educational process could take place prior to the process of obtaining permission, and may be provided prenatally or after the birth of the child.

11.3 CONSENTING NON-ENGLISH SPEAKING SUBJECTS

Federal regulations, 45 CFR 46.116 and 117; 21 CFR 50.25 and 50.27, require that informed consent information be presented in a language understandable to the subject, and in most cases that informed consent be documented in writing. Investigators should consider the ethical and legal ramifications of enrolling a subject when there is a language barrier. If subjects do not have a clear understanding of the consent document or are not able to freely ask questions and understand the answers, then their consent will not be truly informed and legally effective. When subjects/families do not speak English, the use of translated consents is always preferred.

A. Translated Consent Forms

If an investigator anticipates that non-English speaking subjects will be enrolled on a study or if the parents or guardians do not speak English, the consent documents should be translated into the native language(s) of potential subjects and/or parents prior to their enrollment. Protocol-specific foreign language consent and assent forms require IRB approval before being used to enroll study subjects. If the investigator does not initially anticipate enrolling non-English speaking subject(s) but later wishes to do so, the consent and assent forms should be submitted as an amendment with the certification of translation.

B. Use of a Translated Consent Form

The informed consent process for enrolling subjects using a translated consent form must meet the following requirements:

i. The investigator must submit the translated document(s) to the IRB for review and approval with a certificate of translation by the translator indicating that the translation is a true representation of the English version.

ii. The PI or person obtaining consent, through the interpreter, must orally present the IRB approved version of the translated consent to the subject, and the subject must be given a written translation of the consent form to read;

iii. Per Institutional policy, every effort should be made to use a professional interpreter. No patient, family, or friend should be utilized as an interpreter. No child under the age of 18 should ever be asked to interpret. If fluent in the language spoken, the principal investigator or another study team member who is authorized to obtain consent, may present the study information directly to the subject/family. Care should be taken to ensure that the interpreter's relationship with the subject does not adversely influence the subject's ability to make an independent decision regarding participation.

iv. The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved translated version of the consent form;

v. The subject/LAR should sign the translated consent form;

C. Use of a Short Form for Informed Consent

Federal regulations 45 CFR 46.117 (and 21 CFR 50.27) include provisions for a consent process that can accommodate an illiterate subject or a subject who cannot read/understand English. For research studies that may encounter subjects in these situations, the regulations allow for the use of a short form in combination with a verbal presentation of information related to the conduct of the research. The occurrence of the verbal informed consent process is documented via a "short form written consent document" (short form).

The short form states that the elements of informed consent have been presented orally to the subject, and that the key information required by 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The short form does not contain protocol-specific information and should only be used under special circumstances (e.g., the enrollment of illiterate persons or non-English speakers for whom no translated consent form is available) and enrollment of subjects in a study which requires an immediate decision (due to the emergent nature of the research).

The IRB will take into account the complexity of the study and the ability of potential subjects to understand the protocol when presented verbally. The ability to accommodate non-English subjects throughout the course of the research will also be considered to ensure the safety of participants. The IRB must be confident that the research team can readily communicate with participants to assess outcomes and safety.

The use of an interpreter and the "short form" is deemed appropriate for situations where the investigator anticipates that the majority of participants will be fluent in English, however, acknowledges that occasionally non-English speaking patients may be eligible for a research study. ORIC has provided IRB approved translations of a "short form" in several languages (e.g. Spanish, Bosnian, Vietnamese, Polish, Arabic, Russian, etc.) for investigators which can be downloaded from the IRB website.

The informed consent process for enrolling subjects using the short form must meet the following requirements:

i. The PI or person obtaining consent, through the interpreter, must orally present the IRB approved English version of the consent to the subject in a language understandable to the subject, and the subject must be given a written translation of the short form consent document to read;

ii. Per Institutional policy, a professional interpreter should be utilized in the informed consent process. Care should be taken to ensure that the interpreter's relationship with the subject does not adversely influence the subject's ability to make an independent decision regarding participation. Under no circumstances, should an individual under the age of 18 serve as interpreter;

iii. The consent process must be witnessed by an individual who is fluent in both English and the language understandable the subject. The interpreter may serve as the witness;

iv. The IRB shall approve a written summary of what is to be said to the subject or the representative, typically the IRB approved consent English consent form serves as this summary;

v. The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form;

vi. The subject/LAR should sign the translated short form;

vii. The witness to the consent process must sign both the translated short form and the summary (English informed consent form);

viii. A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form must be given to the subject/LAR. Copies of both forms must be placed in the subject's study file and medical record (as applicable).

11.4 CONSENTING SUBJECTS WHO LACK DECISIONAL CAPACITY

If an investigator wishes to enroll adults who lack decisional capacity and is unable to provide informed consent themselves, consent must be obtained from a LAR. For the purpose of this policy, "decisional capacity" is defined as "*the ability to understand and appreciate the nature and consequences of a decision regarding medical treatment and the ability to reach and communicate an informed decision in the matter as determined by the attending physician.*" Subjects may lack decisional capacity due to a number of circumstances, such as severe psychiatric disorders, degenerative diseases affecting the brain, impaired consciousness, etc. However, investigators should note that diagnosis of mental illness or mental retardation is not an automatic bar to a determination of decisional capacity; instead, investigators should consider whether individuals with such diagnoses lack decisional capacity using the previously provided definition.

A. Assessing Capacity to Consent

All adults, regardless of condition or diagnosis of disease should be presumed competent to consent unless there is evidence of cognitive impairment or mental disability. Cognitive impairment refers to a psychological disorder, organic impairment, psychiatric disorder, a medical condition, or developmental disorder that diminishes capacity for judgment and reasoning. Subjects dependent on drugs or alcohol, subjects suffering from degenerative diseases, and terminally ill patients may also be compromised in their decision-making ability. Individuals who are incapable of providing consent cannot be enrolled in a study without the consent of a LAR.

Prior to enrollment, an investigator must assess the potential participant's capacity to consent. To do so, the investigator must determine to the best of his or her knowledge whether the subject understands the risks and benefits of the research, the therapeutic options to research, and the voluntary nature of participation. When making this determination, the investigator should ask open-ended questions of the potential subject. The IRB recommends investigators using the following questions as guidelines to assess potential subjects' capacity to consent:

- What will you be asked to do if you participate in this study?
- What are the potential risks of participating in this study?
- What are the potential benefits of participating in this study?
- How long will you be involved in the study?