## FDA LANGUAGE REGULATIONS

Research - IND (Investigational New Drug) application:

Title 21 of the Code of Federal Regulations of the FDA requires that "… all documentation submitted to FDA has to be in English, its official language…"

### *Non-English Speaking Subjects*

To meet the requirements of 21 CFR 50.20, the informed consent document should be in language understandable to the subject (or authorized representative). When the consent interview is conducted in English, the consent document should be in English. When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate. As required by 21 CFR 50.27, a copy of the consent document must be given to each subject. In the case of non-English speaking subjects, this would be the translated document. While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation.

If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral translation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective. If investigators enroll subjects without an IRB approved written translation, a "short form" written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally. The required signatures on a short form are stated in 21 CFR 50.27(b)(2).

### *21 CFR 50.20 General requirements for informed consent*

The IRB should ensure that technical and scientific terms are adequately explained or that common terms are substituted. The IRB should ensure that the informed consent document properly translates complex scientific concepts into simple concepts that the typical subject can read and comprehend.

Title 21 CFR Part 312, Section 50.20 requires that information provided to study subjects or their representatives be in a "language understandable to the study subjects or to representative of the subject". Inconsistencies found in study procedures may lead to disqualification of the investigator and consequences for the sponsoring company.

Manufacturing

Section 211.25 states that "each person engaged in manufacture processing, packaging, or holding of a drug product shall have education, training, and experience, or a combination thereof to enable person to perform the assigned functions". Thus, training manuals and standard operating procedures are submitted to the FDA in English, but cannot be used to train non-English-speaking personnel. The manuals need to be translated into the language of the people being trained.

Marketing

Title 21, Part 190, Section If any
part of the material submitted is in a foreign language, it shall be
accompanied by an accurate and complete English translation; and

If promotional material or labeling is handled out to consumers in languages other than English, both the English and the Foreign language documents have to be approved by DDMAC in compliance with Part 208 of the Federal Food, Drug, and Cosmetic act. According to the FDA section 201(m) of the Federal Food, Drug, and Cosmetic Act, labeling means: "all brochures, booklets, mailing pieces, file cards, catalogs, letters, medication guides, etc. "This regulation states that medication guides shall be written in non-technical, understandable language and shall not be promotional in tone or content.