It is essential that non-English speaking individuals and those individuals with limited English language proficiency have equal access to research protocols. Since research protocols offer a potential for direct benefit that may only be available within the context of the research, the exclusion of non-English speaking individuals becomes ethically problematic. Baystate Health provides qualified interpreters and certified translations through the Interpreter and Translation Services Department.

Per regulation, the informed consent process must be done in a language that is understandable to the subject. Based on our patient population, the Institutional Review Board (IRB) requires that most consent forms (CF) and subject research materials be fully translated into Spanish. In addition, researchers should plan in advance so that an interpreter is available as needed for the consent process and ongoing interactions with the subject. To ensure the accuracy of interpretation, unless a provider is a native fluent speaker of the patient’s language, an interpreter must be arranged for by contacting Interpreter and Translation Services.

The criterion for requiring translations of consent forms and other research materials is based on the native language of the expected study population. If the expected study population has a >5% native language other than English (which is the case of the Spanish-speaking population in Springfield), then studies must have the consent document and research materials translated into that language. This criterion is generally waived if it involves a pilot study of <10 patients with no expectation of benefit or a study that has an expected enrollment period of <42 days. If someone who does not speak English becomes available for a study that fits the above description, then the short form of the CF can be used.

Only the final IRB approved version of the CF and other subject research materials will be translated by Interpreter and Translation Services. Before submitting to the IRB please be aware of the following:

- Review your original document for grammatical errors and spelling prior to its submission. Please explain unusual jargon, acronyms, or abbreviations.
- Decide if any portion of this document should remain in English. For instance, although the title of the document will be translated, its original English title will appear below the translated title in smaller font, followed by the language into which it has been translated. Example:
  
  Consentimiento General para Cuidado y Tratamiento
  (General Consent for Care and Treatment – Spanish)

- Signature and witness lines are usually left in English so that nurses and other providers will know where to sign. Are there other areas that staff need to read or complete that should also stay in English?
- Interpreter and Translation Services will translate or contract to translate the text of your document. If there is difficult or unusual formatting or if there is graphic design involved, these translations should be discussed with the Production Coordinator (ext. 4-7638) in the office of Strategic Marketing and Communications.
- The translated document will be returned to you looking as similar as possible to the English original. However, because it often takes more words to express something in another language, your translated document may end up being longer than your original document.
The following process is to be employed for the translation of final IRB approved documents:

- Once final approval by the IRB has been granted, the IRB will forward the electronic version of the document to Interpreter and Translation Services.
- The IRB will submit the documents by e-mail to “Translation Services” on the internal e-mail list or translations@bhs.org. If additional information or discussion is needed, the Interpreter and Translation Services Supervisor can be reached at extension 4-3748.
- Interpreter and Translation Services has a turn around time of approximately six weeks. If there are multiple documents, Interpreter Services could take a little longer to complete all translations.
- Once the translations are complete, Interpreters and Translation Services will send the document back to the IRB.
- The IRB will then forward the translated document to the study contact or principal investigator who will have the responsibility of submitting the document as an amendment to the IRB for approval.
- The IRB will conduct the review of the translated document via an expedited review and approval will be notified via the IRBNet.
- While waiting for documents to be translated, investigators will be able to begin recruiting non-English speaking participants by using the short form available on the IRB website. However, once the translated CF is approved by the IRB, this CF must be signed by the participant on the next study visit.

Translation Waiver
Some study sponsors have access to certified translations and like to provide their own translated research materials. The IRB will accept these translated research materials but they must be accompanied by a certificate of translation. If you know that your sponsor will be providing this service, or if the study meets the translation waiver criterion (as described on the previous page), a memo must be attached to the IRB submission with either the sponsor notification or the waiver request justification.

Costs:
Effective October 1, 2010, industry funded studies will be assessed a $750 fee for consent form translations when required per IRB guidelines. This fee should be included in project budgets and will be billed directly to the sponsor through the Grants Management Accounting System. The costs associated with providing translated documents for investigator-initiated and internally funded projects will be absorbed by Academic Affairs.

Other Languages and Information on Short Forms:
A short form consent document may be utilized when a long from is not available in the participants language. Short form consents will be available in other languages from the IRB website. The short form consent contains a summary of the informed consent elements found in the CF long form. The short form consent is to be administered with an oral presentation/summary of the IRB approved long CF. As with the long form, when the short form is used, an interpreter arranged for through Interpreter and Translation Services must be present. The short form is then signed by the subject and the witness. The CF long form is signed by the witness and the person obtaining consent. A copy of both the short form and CF long form are given to the subject.

Interpreter and Translation Services Department Contact Information:
- Inpatient Studies: Extension 4-5419
- Outpatient Studies: If the department you are working with schedules medical interpreters through Access Services, please call the Access Services number for that area to book an interpreter. If your department does not book patient appointments through Access, please call Interpreter and Translation Services directly at 4-5419

For further information please see: