

HAC Policies and Procedures

Non-English Speaking Subjects

HAC Policies and Procedures

Non-English Speaking Subjects

Federal regulations stipulate that any research involving non-English speaking subjects in any manner must have specific approval for their participation.

If Non-English Speaking Subjects Are Part Of The Primary Target Pool, Do We Have To Explain and Present The Study In A Language That Is Understandable To The Subject?

Yes, per the federal regulation 21CFR46 50.20. All written documents, e.g., informed consent, children's assent, subject diary cards, medication and dosing instructions, etc., must be written in the subject's native language to help ensure that the subject can fully understand the study.

Can Subjects Be Excluded From The Study If They Are Non-English Speakers?

Individuals may not be excluded from the study based on their inability to speak, read or write in English. They must not be enrolled until the HAC has approved an informed consent process that includes translations into their native language. The PI must also document how information will be communicated to these subjects.

What About Documents Used For the Study such as ICD and/or CAD, Questionnaires, Flyers, Prescriptions, Instructions?

The investigator must submit the English language version of all document(s) to the HAC for approval with the initial submission or as an amendment to an approved protocol.

What Forms Must Be Submitted?

After the HAC approves the English language version of the document(s), then the investigator must submit the translated document(s) in the foreign language for HAC approval. A certification statement by the individual or professional translation service that performed the translation must be included with the document(s) as well as a completed HAC Form 113, Amendment Submission Form.

What About The Costs Associated With Professional Translators?

The costs associated with the professional translation service are to be borne by the investigator, either through negotiation with the sponsor or other funding source. The investigator's department will be responsible for these costs if the investigator does not have any external funding.

Will The HAC Require Any Additional Safeguards For Non-English Speaking Subjects?

The HAC may require a certified interpreter based on the risk level of the research study.

HAC Policies and Procedures

Does The HAC Have A Listing Of Translations Service Companies?

Yes. Please remember that these sites are provided primarily for your information as the HAC does not endorse any translations service companies.

Translations Service Companies

[Click2Translate](#)

[Translated.Net](#)

[BeTranslated](#)

[Global Language Solutions](#)

Who Do I Contact if I Have Any Questions?

For additional guidance, contact the HAC Administrative Office at HAC@mcg.edu or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.