## **Using Family Members and Study Staff as Interpreters During Research Procedures, Including Consent Process, in Research Conducted at Emory**

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#### Background and Challenges Related to Interpretation and Research Studies

During the conduct of research, there may be times when an investigator encounters potential participants who do not speak English or who have limited English proficiency (“persons with LEP”). These individuals should generally be allowed participate in research studies, absent compelling reasons to exclude them, in accordance with the Belmont Report principle of Justice. Research quality is enhanced when studies are conducted across a wide range of potential beneficiaries. Restricting participation based on language may reduce generalizability of research as well as create an injustice when persons with LEP cannot get access to investigational therapeutic approaches.

When enrolling persons with LEP, investigators are required to offer the service of an interpreter to help in the consent process. Investigators may use the services of an in-person interpreter, but the decision to do so can lead to delays in enrollment due to a general lack of availability of in-person interpreters. Alternatively, investigators may use an interpreter via phone, which alleviates the time delay. However, this approach can be less effective at providing a full explanation of the research project to potential participants.

Some studies show that satisfaction for non-English speaking persons and persons with LEP is higher when they undergo the consent process with the use of an in-person interpreter versus an interpreter via phone. In a study by Kuo and Fagan, the use of an in-person interpreter was preferred over the use of an interpreter via phone. In fact, “presence in room” was given a satisfaction rate of 78.9%[[1]](#footnote-1). This rate was comparable to the satisfaction rate where a family member was used as the interpreter.

Is it acceptable to use a family member as an interpreter during the consent process or research activities with the agreement of the potential research subject, or do ethical issues prevent it? Is it permissible per law and regulations for a study staff member to serve as an interpreter? The goal of this guidance document is to shed light on Emory IRB’s interpretation of these issues, taking into consideration the perspectives of professional interpreters, investigators, and IRB chairs and ethicists, and after reviewing the available policies of other institutions (see Appendix 1).

#### What does the law say about this?

Although federal law does not provide much guidance on the use of interpreters for non-biomedical research, several federal statutes apply to the field of spoken language interpretation as it relates to healthcare, and federal guidance further supplements the statutory directives. The 1964 Civil Rights Act[[2]](#footnote-2), Title VI, prohibits discrimination based on race, color, and national origin in programs and activities receiving federal financial assistance.[[3]](#footnote-3) Title VI requires that medical providers, as recipients of federal financial assistance, make interpretation services free and available so that persons with LEP can access health care on par with the care given to English speakers.[[4]](#footnote-4)

The U.S. Department of Health and Human Services has issued policy guidance for Title VI compliance[[5]](#footnote-5), which states that persons with LEP must be afforded a meaningful opportunity to participate in programs that receive Federal funds, including health care programs and that policies and practices may not deny or have the effect of denying persons with LEP equal access. As a result, persons with LEP must be notified of the availability of free interpreting services and that providers are prohibited from requiring friends or family members of a person with LEP to act as interpreters. It stipulates that interpreters must be competent in medical terminology and have a full understanding of the concepts of confidentiality and impartiality.

Section 1557 of the Affordable Care Act[[6]](#footnote-6) also prohibits discrimination in health care on the basis of national origin by covered entities like Emory (covered entities are defined in this section as those that do federally-funded “health research;” i.e., not just Emory Healthcare). Entities must make interpretation services available so that LEP patients can access a standard of health care equivalent to that of English speakers.

The statute defines a qualified interpreter as “an individual who has the characteristics and skills necessary to interpret for an individual with a disability, for an individual with limited English proficiency, or for both.” To be considered “qualified,” the interpreter must adhere to interpreter ethics and have an understanding of and dedication to maintaining client confidentiality.

45 CFR § 92.201[[7]](#footnote-7), a federal code provision which addresses the ways in which covered entities like Emory must provide meaningful access of health services to persons with LEP, further restricts the use of certain individuals to act as interpreters. This provision states that covered entities shall not require a person with LEP to provide his or own interpreter and shall not allow any of the following to act as interpreters:

* an adult accompanying the person with LEP
* a minor child
* non-qualified bilingual/multilingual staff

Although the law prohibits use of the above categories of people to act as interpreters, there are some exceptions:

* Accompanying adults: An adult accompanying the person with LEP may act as an interpreter only 1) in an emergency involving an imminent threat to the safety or welfare of an individual or the public when there is no qualified interpreter immediately available, or 2) where the person with LEP specifically requests that the accompanying adult, having agreed to provide such assistance, interpret or facilitate communication and reliance on that adult is appropriate under the circumstances. 81 FR 31417-31418[[8]](#footnote-8) further clarifies that this category of individuals is meant to cover family members and friends of persons with LEP as well as other kinds of informal interpreters and reiterates that covered entities may not rely on family members, friends, or other informal interpreters unless the situation meets one of the exceptions described in this section.
* Minor children: A minor child may act as an interpreter only in an emergency involving an imminent threat to the safety or welfare of an individual or the public and where there is no qualified interpreter for the person with LEP immediately available.
* Staff members: A staff member may communicate with an LEP patient only if he/she constitutes a “qualified bilingual/multilingual” staff member. “Qualified bilingual/multilingual staff” means the staff member is a member of the covered entity's workforce who is designated by the covered entity to provide oral language assistance as part of the individual's current, assigned job responsibilities. The staff member must have demonstrated to the covered entity that he or she is 1) proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology; and 2) able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.[[9]](#footnote-9) 81 FR 31417 reiterates that staff members must meet the definition of “qualified bilingual/multilingual staff” in order to communicate with LEP patients. It warns against using “staff members who possess only a rudimentary familiarity speaking and understanding a non-English language,” stating that it “can result in miscommunication and the omission of relevant information, which can in turn result in a lower standard of care and raise questions about whether consent provided by an individual with limited English proficiency was truly informed.”

#### Issues with family members as interpreters

Per 81 FR 31418: “In many circumstances, family members…are not competent to provide quality, accurate oral interpretation. For communications of particularly sensitive information, oral interpretation by an individual’s family…often also implicates issues of appropriateness, confidentiality, privacy, and conflict of interest.” Family members are seen by some as able to address these cultural and language barriers. However, having a family member does not guarantee that that the translation will be done correctly. Certain cultural and family relationships may cause withholding of information that may be important to make a decision about participation. Additionally, family members may not have adequate English language knowledge to understand or translate technical or difficult medical or research information. Family members, especially minor children, may be put in a difficult position if they have to explain something difficult to the patient or if the information itself is complicated to understand in any language.

#### Issues with the use of research staff as interpreters

Per 81 FR 31391[[10]](#footnote-10), using study team members may pose a conflict of interest when presenting information to the person participating in a research study. Per 81 FR 47317, staff members may not possess competence in the skill of interpreting, especially in non-verbal skills, nor have knowledge of generally accepted principles of interpreter ethics.

Finally, when a verbal interpretation is used instead of a fully translated consent form, there is no objective source of information for the subject to review, other than the interpreter’s statements.

**What are Emory Healthcare and Children’s Healthcare of Atlanta’s policies on the use of interpreters in medical care?**

For medical treatment, Emory University follows Title VI and the CLAS Standards from the office of Minority Health. Emory Healthcare provides video remote interpreting for American Sign Language, Spanish, Korean and Vietnamese on-site interpretation. In addition, telephonic interpretation for over 200 languages is available from agency interpreters requiring at least 2 hours in advance. For some languages, the interpreter needs 24-hour advance notice.[[11]](#footnote-11)

Emory Healthcare tries to accommodate the use of non-professional interpreters by having a policy defining how they determine when a staff member is “qualified” to interpret. This policy must be followed when doing research at Emory Healthcare[[12]](#footnote-12)

Children’s Healthcare of Atlanta also follows Title VI and the CLAS Standards from the office of Minority Health. CHOA provides Spanish interpreters, other foreign language interpreters, Sign language interpreters, Phone interpreters, written translation services and cultural resources. [[13]](#footnote-13) CHOA has a policy that family members may not be interpreters when medical procedures are involved. If you work at CHOA, please make sure you access their current policy.

#### What does this mean for research?

In research, the stakes are higher, because the interventions are not required for clinical care and there may be no therapeutic benefit. A person considering participation in a study must thoroughly understand that the proposal is research, not patient care, the study aims, procedures, risks and benefits, alternatives to participation and any other information that could affect their decision. The potential participant should also be free from the potential bias of family members.

There are potential negative consequences of prohibiting the use of family members or research team members as interpreters for research. During the IRB discussion with interpreters, ethicists and IRB members, the following was discussed:

* Potential sample bias, if LEP are excluded due to lack of professional interpreters. This could be alleviated by accessing current resources available at Emory and Children’s Healthcare of Atlanta.
* Delays due to being second priority for interpreter resources, behind medical treatment.
* Additional cost for studies that do not have access to free interpreter services. This would not apply for in-hospital studies where translation service is available.
* Using a phone translation service could pose potential risks, as it was observed by our meeting participants that subjects may ask for clarification via phone less frequently when compared with in-person interpreters, and the interpreter cannot help with conveying visual information. This could be mitigated by the study team asking questions about study details to assess understanding.

Despite these issues, the bioethics consensus is that family members should not be used as interpreters, as a rule. Because of regulatory requirements, non-qualified interpreters should not be used when the study involves medical treatment as part of a research study.

#### Emory IRB Guidance

The Emory IRB, consistent with Title VI and the CLAS Standards from the office of Minority Health, considers that people with LEP must have the opportunity to understand what they are being asked to do in the context of a research study. Using a friend or family member as an interpreter introduces conflicts of interest that may adversely impact the rights and welfare of potential study participants. The same can be said when using study team members to interpret instead of a qualified interpreter when a study involves medical treatment.

When conducting research within any healthcare facility, you must follow the policies of that facility, notwithstanding the below. Emory Healthcare has created a policy defining how they determine the “qualifications” of interpreters.

The following will guide the Emory IRB’s review of research involving participants with limited English proficiency, other than in the emergency scenarios mentioned above:

NOTE: Studies “covered by Section 1557” include any research that takes place at an institution that is covered by that Section (e.g. Emory Healthcare settings), and any health-related research that is federally funded.

* For research involving treatment (as it is the case of a clinical trial), the IRB requires the use of a trained and qualified interpreter during consent and re-consent of subjects, and when performing any activity as part of the research study.
* For studies that are NOT covered by Section 1557, and that do not involve treatment as part of the research, the IRB may allow for study team members, who are proficient in the language of the subject, to be used as interpreters, if there is documentation that they are truly capable to interpret for subjects. It is expected that the team member is truly proficient and culturally aware. The study team should document that the study member has these qualifications for the research record. Family members and friends cannot serve as interpreters for these discussions.
* Minors are not allowed to serve as interpreters under any circumstance, other than the emergency scenarios mentioned above.
* The IRB may allow adult family members and staff members to serve as interpreters for minimal risk, socio-behavioral or non-clinical health studies that are NOT covered by Section 1557, where language barriers would not have any effect on data that will be collected, except during consent discussion. Study team members should explain the proposed plan for the use of adult family members in the protocol submission.
	+ For example, a socio-behavioral or public health study where the consent form (or script) and study instruments (e.g. surveys) are fully translated into the participant’s language. In this scenario, an adult family member or other non-professional interpreter is allowed to help with administrative/logistical conversations during study visit(s), after the consent discussion has taken place with a qualified interpreter.

#### Appendix 1 – Other Institutional Policies (as of 2016)

| **School** | **Interpreters** | **Witness** | **Notes** |
| --- | --- | --- | --- |
| University of Virginia | Yes - Patient request |   | A patient's relative or family member as an interpreter of healthcare information. A patient's relative or friend shall be used as an interpreter only at the request of the patient and only if the use will not compromise the effectiveness of the medical services provided or jeopardize the patient's privacy regarding sensitive medical information. Use of minor children as interpreters is prohibited, even if such use is the patient's preference. |
| UCLA | Yes - if qualified |   | Page 6. Consider issues of privacy if family members are asked to translate. If an adult family member is asked to translate, they must be qualified to translate (e.g. health professional and/or knowledgeable in medical terminology) |
| Ohio State | Yes - Emergency only |   | Family members may serve as interpreters only in emergency life-threatening situations. |
| Stanford | Yes |   | Allows the use of a family member as an interpreter only if the participant declined the use of a hospital interpreter. |
| Tufts | Yes | No | Per page 89 of their IRB Operations Manual, family members can act as the interpreter/interpreter however they cannot also act as the witness. |
| Iowa | Yes |   | A bilingual family member, and significant others, may serve as interpreters. |
| Boston University | Yes |   | Adult family members can serve as the interpreter. For minimal risk studies. |
| Children’s Healthcare of Philadelphia | Yes | Yes | An adult family member (who is not the legally authorized representative), e.g. an aunt, uncle, older sibling, or a neighbor can serve as an interpreter and witness. |
| University of Georgia | Yes |   | Sections 4.3.3 and 4.3.4. The interpreter may be a member of the research team, family member, or friend of the subject. |
| University of Kansas | No |   | Family members cannot serve as oral interpreters. |
| University of California-Irvine | No | No | Family members cannot serve as interpreters or witness due to potential bias. |
| Yale | No | Yes | Family members may serve as a witness but not as an interpreter. |
| University of Pittsburgh | No |   | Family members are not permitted to serve as the interpreter because they may substitute their views for those of the potential subject. |

| Duke University | No |   | The oral presenter cannot be related to, or a close associate of, the subject or LAR. |
| --- | --- | --- | --- |
| St. Josephs Health (California) | No | No | Page 5.  A witness must be neutral, such as an adult who is not a member of the research team and who is not a family member of the participant. |
| University Hospitals (Ohio) | No | No | Family members, friends etc. may not act as an official interpreter for the purposes of enrollment. |
|   |   |  |  |
| **Totals** |  |  |
| Yes | 9 |  |  |
| No | 7 |  |  |
| Non-Specific\* | 11 |  |  |

**Stanford** – allows the use of a family member as an interpreter only if the participant declined the use of a hospital interpreter.
Link: <http://humansubjects.stanford.edu/new/resources/consent/short_form_consent_process.html>

**The Ohio State University** – Family members may serve as interpreters only in emergency life-threatening situations.
Link: <http://orrp.osu.edu/files/2011/10/Short-Form-Consent.pdf>

**Tufts** – Per page 89 of their IRB Operations Manual, family members can act as the interpreter/interpreter however they cannot also act as the witness.
Link: <http://viceprovost.tufts.edu/HSCIRB/files/IRB_Operations_Manual.pdf>

**Iowa** – a bilingual family member, and significant others, may serve as interpreters.
Link: <http://hso.research.uiowa.edu/guidance-principal-investigators-and-research-team-members>

**Boston University** – Adult family members can serve as the interpreter. For minimal risk studies.
Link: <http://www.bumc.bu.edu/irb/files/2008/12/short-form-interpreter-table.pdf>

**University of Kansas** – Family members cannot serve as oral interpreters.
Link: [http://www.kumc.edu/Documents/hrpp/Topical%20Guidance/Short%20Form%20Consent%20Instructions.pdf](http://www.kumc.edu/Documents/hrpp/Topical%2520Guidance/Short%2520Form%2520Consent%2520Instructions.pdf)

**Rutgers** – Family members can only serve as an interpreter in emergency situations.
Link: [http://rbhs.rutgers.edu/hsp/guidance/Guidance\_UMDNJ%20Non-English%20Obtaining\_Documenting\_Consent\_NonEnglish\_Speaking\_guidance.pdf](http://rbhs.rutgers.edu/hsp/guidance/Guidance_UMDNJ%2520Non-English%2520Obtaining_Documenting_Consent_NonEnglish_Speaking_guidance.pdf)

**University of California-Irvine** – Family members cannot serve as interpreters or witness due to potential bias.
Link: <http://research.uci.edu/forms/docs/irb-forms/doc-depot-short-form-consent.pdf>

**Yale** – Family members may serve as a witness but not as an interpreter.
Link: <http://www.yale.edu/hrpp/policies/documents/200GD2nonenglishspeakers6-27-14.pdf>

**University of Virginia** - a patient's relative or family member as an interpreter of healthcare information. A patient's relative or friend shall be used as an interpreter only at the request of the patient and only if the use will not compromise the effectiveness of the medical services provided or jeopardize the patient's privacy regarding sensitive medical information. Use of minor children as interpreters is prohibited, even if such use is the patient's preference.
Link: [http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=27&cad=rja&uact=8&ved=0CEYQFjAGOBQ&url=http%3A%2F%2Fwww.virginia.edu%2Fvpr%2Firb%2FHSR\_docs%2FForms%2FShort\_form\_insturctions-1.doc&ei=\_YsRVc64FoWuggT-4ICgDA&usg=AFQjCNFiGBuhqxAI\_uPi2hC4HeH2mh6zkQ&bvm=bv.89184060,d.eXY](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=27&cad=rja&uact=8&ved=0CEYQFjAGOBQ&url=http%253A%252F%252Fwww.virginia.edu%252Fvpr%252Firb%252FHSR_docs%252FForms%252FShort_form_insturctions-1.doc&ei=_YsRVc64FoWuggT-4ICgDA&usg=AFQjCNFiGBuhqxAI_uPi2hC4HeH2mh6zkQ&bvm=bv.89184060,d.eXY)

**University of Pittsburgh** – Family members are not permitted to serve as the interpreter because they may substitute their views for those of the potential subject.
Link: <http://www.irb.pitt.edu/sites/default/files/nonenglishspeaking_4.1.2014.pdf>

**Duke** – The oral presenter cannot be related to, or a close associate of, the subject or LAR.
Link: <http://irb.duhs.duke.edu/wysiwyg/downloads/Non_English-Speaking_Subjects_Translation_Policy.pdf>

**St. Joseph Health (California)** – Page 5. A witness must be neutral, such as an adult who is not a member of the research team and who is not a family member of the participant.
Link: <http://www.stjhs.org/documents/Clinical-Research/Informed-Consent-Guidance.pdf>

**Children’s Hospital of Philadelphia** - An adult family member (who is not the legally authorized representative), e.g. an aunt, uncle, older sibling, or a neighbor can serve as an interpreter and witness.
Link: <https://irb.research.chop.edu/short-form-consent>

**UCLA** – Page 6. Consider issues of privacy if family members are asked to translate. If an adult family member is asked to translate, they must be qualified to translate (e.g. health professional and/or knowledgeable in medical terminology)
Link: <http://ora.research.ucla.edu/OHRPP/Documents/Policy/9/NonEnglish_Participants.pdf>

**University Hospitals (Ohio)** – Family members, friends etc. may not act as an official interpreter for the purposes of enrollment.
Link: <http://www.uhhospitals.org/clinical-research/institutional-review-board/frequently-asked-questions/inclusion-of-non-english-speaking-persons-in-research>

**University of Georgia** – Sections 4.3.3 and 4.3.4. The interpreter may be a member of the research team, family member, or friend of the subject.
Link: <http://research.uga.edu/docs/policies/compliance/hso/IRB-Documentation-of-Informed-Consent.pdf>

**Non-specific:**
University of southern California
Fred Hutchinson CRC
University of South Florida
Johns Hopkins
University of Washington
Vanderbilt University
University of North Carolina
University of Utah
University of Miami
Columbia University
Mayo Clinic

1. Kuo D and Fagan M. *Satisfaction with Methods of Spanish Interpretation in an Ambulatory Care Clinic*. J Gen Intern Med 1999; 14:547-550. [↑](#footnote-ref-1)
2. <https://www.ourdocuments.gov/doc.php?flash=true&doc=97&page=transcript> [↑](#footnote-ref-2)
3. In 1975, the U.S. Supreme Court ruled that language and national origin are so closely interrelated that they should be treated as equivalent. [↑](#footnote-ref-3)
4. Executive Order 13166, thereafter required every federal agency to examine the services it provides, identify any need for services to persons with LEP, and develop and implement a system to provide such services so they can have meaningful access to them. [↑](#footnote-ref-4)
5. <https://www.hhs.gov/civil-rights/for-individuals/special-topics/needy-families/civil-rights-requirements/index.html> [↑](#footnote-ref-5)
6. <https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html> [↑](#footnote-ref-6)
7. <https://www.law.cornell.edu/cfr/text/45/92.201> [↑](#footnote-ref-7)
8. <https://www.gpo.gov/fdsys/pkg/FR-2016-05-18/html/2016-11458.htm> [↑](#footnote-ref-8)
9. <https://www.gpo.gov/fdsys/pkg/CFR-2016-title45-vol1/pdf/CFR-2016-title45-vol1-sec92-4.pdf> [↑](#footnote-ref-9)
10. <https://www.federalregister.gov/d/2016-11458/p-260> [↑](#footnote-ref-10)
11. <https://www.emoryhealthcare.org/patients-visitors/interpretation.html?_ga=2.162217979.61332055.1530792342-531137430.1529932255> [↑](#footnote-ref-11)
12. Policy: Language Skills Assessment for Qualified Dual Role Interpreters and Bilingual/Multilingual Employees at [http://euhnotes.eushc.org/CLH/CLHPOLCY.NSF/(Table+of+Contents)/D11DEBA3F1F446828525823400455D19?OpenDocument](http://euhnotes.eushc.org/CLH/CLHPOLCY.NSF/%28Table%2Bof%2BContents%29/D11DEBA3F1F446828525823400455D19?OpenDocument) [↑](#footnote-ref-12)
13. <http://www.choa.org/Patients-Families/During-Visit/Translating-and-Interpreting-Services> [↑](#footnote-ref-13)