**Requirements for Ensuring Compliance with the Short Form Consent Process**

**For Non-English Speakers**

If your study targets a particular non-English speaking population, or if you expect to enroll more than 2 people of a specific non-English speaking population, you may be required to translate consent documents into that particular language. Please review the [IRB Policies and Procedures](http://www.irb.emory.edu/documents/PoliciesAndProcedures.pdf) for information regarding the translation policy.

Use of a short form is allowed when:

1. The Study Population page in eIRB includes “Subjects who are not able to clearly understand English”;
2. An Emory-provided short form is used or the IRB has approved a research team-provided short form;
3. Use is not expressly prohibited by the IRB; and
4. The study sponsor allows use of a short form.

If any of the above conditions are not met, an amendment requesting permission must be submitted and approved by the IRB prior to using a short form.

**Procedures for Using a Short Form:**

* No more than 2 short forms of the same language should be used for enrollment in a 12 month period. Any additional uses require consultation with the Emory IRB office.
* The **person obtaining consent** should ensure that contact information is noted on the short form in the blanks provided, with a name on the first line and phone number on the second line.
* A **translator** must read the English consent form and verbally translate the information to the subject or the subject’s legally authorized representative (LAR). If the subject is a child six years or older, the approved assent documents should also be verbally translated. The consent process must be witnessed by someone who is fluent in both English and the subject’s language. The **translator** may serve as the **witness** unless he or she is a member of the study team.
* A **witness,** who may also be the **translator** but cannot be affiliated with the study, must sign both the short form consent and the English consent (signing anywhere on the English consent signature page is acceptable).
	+ Studies with optional consent items: The **translator** must write a comment on the last page of the short form to indicate that the **subject** made specific choices. The **translator** should indicate the **subject’s** choices on the English consent form and include the **translator’s** initials beside each choice.
* The study **subject** or LAR must sign the short form consent (not the English version). If an LAR provides consent, it should be recorded as a note in the **subject’s** research record. If enrolling a child, the assent form is verbally translated but the child does not sign any documents.
* The **person obtaining consent** must sign the English version of the IRB-approved consent form.
* The study **subject,** or LAR, must receive copies of the following:
	+ The short form consent signed by the subject and the witness
	+ The IRB-approved English consent signed by the witness and person obtaining consent
* The original signed and dated IRB-approved English consent form should be filed *with* the original signed and dated short form consent in the **subject’s** research record.

**Đại học Emory**

**Chấp thuận Tham gia Nghiên cứu**

Quý vị được đề nghị tham gia một cuộc nghiên cứu.

Trước khi quý vị đồng ý, nhà nghiên cứu phải thông báo cho quý vị về (i) mục đích, thủ tục và thời gian nghiên cứu; (ii) mọi thủ thuật mang tính thực nghiệm; (iii) mọi nguy cơ, khó chịu và lợi ích có thể dự đoán trước hợp lý của nghiên cứu này; (iv) mọi thủ thuật hoặc điều trị thay thế có lợi ích tiềm tàng; và (v) tính bảo mật sẽ được duy trì như thế nào.

Khi thích hợp, nhà nghiên cứu cũng phải thông báo cho quý vị về (i) bất kỳ sự đền bù hoặc điều trị y khoa nào sẵn có nếu gặp tổn thương; (ii) khả năng xảy ra những nguy cơ có thể dự đoán trước; (iii) những trường hợp nhà nghiên cứu có thể ngừng sự tham gia của quý vị; (iv) chi phí bổ sung cho quý vị; (v) điều gì xảy ra nếu quý vị quyết định ngừng tham gia nghiên cứu; (vi) khi nào quý vị được thông báo về những phát hiện mới có thể ảnh hưởng đến ý định tham gia của quý vị; và (vii) bao nhiêu người sẽ tham gia vào nghiên cứu này.

Nếu đồng ý tham gia, quý vị sẽ được cấp một bản sao có chữ ký của tài liệu này và bản tóm lược nghiên cứu.

Quý vị có thể liên lạc với \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ theo số \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ bất kỳ lúc nào quý vị có thắc mắc về nghiên cứu này.

Quý vị có thể liên lạc với Đại học Emory IRB theo số 404-712-0720 bất kỳ lúc nào quý vị có thắc mắc về quyền với tư cách là đối tượng tham gia nghiên cứu hoặc điều cần làm khi quý vị bị tổn thương.

Việc tham gia vào nghiên cứu này là tự nguyện và quý vị sẽ không bị phạt hoặc mất quyền lợi nếu quý vị từ chối tham gia hoặc quyết định ngừng tham gia nghiên cứu.

Ký tên vào tài liệu này có nghĩa là nghiên cứu này, bao gồm những thông tin nói trên, đã được mô tả cho quý vị bằng lời nói và quý vị tự nguyện đồng ý tham gia.

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chữ ký của người tham gia ngày

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chữ ký của người làm chứng ngày