**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.

**Universidad de Emory**

**Consentimiento para participar en un estudio de investigación**

Por medio de este documento le estamos invitando a que participe en un estudio de investigación.

Antes de aceptar, el investigador debe hablarle sobre (i) los objetivos, procedimientos y duración de la investigación; (ii) cualquier procedimiento que sea experimental; (iii) cualquier riesgo, molestia y beneficio de la investigación, que se puedan anticipar; (iv) cualquier procedimiento o tratamiento alternativo que le pueda beneficiar; y (v) de qué manera se mantendrá su confidencialidad.

Cuando corresponda, el investigador también debe hablarle de (i) cualquier compensación o tratamiento médico disponible en caso de que ocurra una lesión; (ii) la posibilidad de riesgos imprevistos; (iii) las circunstancias en las que el investigador puede interrumpir su participación; (iv) cualquier costo adicional que deba pagar; (v) lo que ocurre si decide interrumpir su participación; (vi) cuándo se le comunicarán los descubrimientos nuevos que pudieran afectar a su deseo de participar; y (vii) cuántas personas participarán en el estudio.

Si acepta participar, se le entregará una copia firmada de este documento y un resumen escrito de la investigación.

Puede comunicarse con\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ al \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ cada vez que tenga preguntas sobre la investigación.

Puede comunicarse con Universidad de Emory al 404-712-0720 si tiene preguntas sobre sus derechos como participante de una investigación o qué debe hacer si sufre una lesión.

Su participación en esta investigación es voluntaria y no sufrirá ningún castigo ni perderá beneficios si se niega a participar o decide interrumpir su participación.

Si firma este documento significa que se le ha explicado de manera oral el estudio de investigación, incluida la información mencionada arriba, y que acepta participar voluntariamente.

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Firma del participante Fecha

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Firma del testigo Fecha