**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.

埃默里大学 (Emory University)

参与研究的同意书

您受邀参加一项试验研究。

在您同意参加之前，研究员必须告诉您 (i) 研究的目的、程序和持续时间；(ii) 任何试验性程序；(iii) 任何有理由预见的研究风险、不适和益处；(iv) 任何可能有益的替代程序或治疗方案；以及 (v) 将如何保密。

在适用情况下，研究员还必须告诉您 (i) 如果出现损伤，您可以获得的任何补偿或治疗；(ii) 出现意外风险的可能性；(iii) 研究员在什么情况下可能让您停止参与研究；(iv) 研究给您带来的任何额外费用；(v) 如果您决定停止参与研究会怎样；(vi) 您何时会被告知可能影响您的参与意愿的新发现；以及 (vii) 会有多少人参与研究。

如果您同意参与，您必须获得此文件的一份签名副本以及本研究的一份书面摘要。

如果您对研究存在任何疑问，您可以随时联系\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_，电话：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_。

如果您对于作为研究受试者的权利或如果受到损伤应该怎么办存在疑问，您可以联系埃默里大学的IRB，电话：404-712-0720。

您参与本次研究纯属自愿，如果您拒绝参与或决定停止参与本次研究，均不会遭到处罚或失去权益。

签署本文件表明已经有人向您口头说明了试验研究的情况（包括上述信息），并且您自愿同意参与研究。

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