

## Back Translation for Quality Control of Informed Consent Forms

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FDA regulations and ICH guidelines both require that "the information that is given to the subject or the representative shall be in language understandable to the subject or the representative."<sup>1,2</sup> Obviously, if an Informed Consent Form (ICF) is written in a language that the subject does not understand, it must be translated into a language the subject does understand.

ICFs are highly technical documents, so careful translation by certified medical translators is essential. Translation errors can change the meaning of important content, causing potential subjects to receive inaccurate information. They can also confuse meaning, so the ICF is more difficult to understand.

Many professional translation companies and independent translators are well-qualified to translate ICFs. However, even with certified medical translators, errors can occur because:

- Translation is more of an art than a science.
- Translators are unlikely to specialize in the specific medical condition under study.
- Time and money are usually limited.

In a normal translation process, the translator translates the document; an editor then reviews the translation and makes corrections. A more robust process includes "back-translation", whereby a second translator translates the foreign language ICF back to the original language. The back translator must have excellent command of the foreign language as well as being a native English medical translator, and perform a more literal translation than normal. The original and back-translated versions of the ICF can be compared side-by-side by the original authors of the document or the IRB. Back-translation addresses the first two causes of error cited above, but at the cost of money and time.

Table 1 presents three paragraphs from a fictional English-language ICF along with two unedited and one edited translation into Spanish. Table 2 presents the respective translations back into English.

Comparing the unedited back translations to the original text reveals:

- As indicated by the highlighted words, both translations include substantive changes. Some of these changes, such as deleting the word "experimental" or adding the word "suffering", change the meaning in important ways. Others, such as changing "hair growth" to "capillary growth" are medically incorrect. Others, such as "experimental blood", make no sense.
- Spanish and English have different grammatical structures, so the numerous changes in wording and phrasing may or may not reflect changes in readability.
- The error rate suggests that quality control is essential.
- The translations have entirely different errors. The errors in a specific translation are thus unpredictable.

The edited translation (2a) makes numerous phrasing changes, but corrects none of the substantive changes. Table 3 describes the substantive changes. It demonstrates that back-translations are not definitive, but can be used to identify possible problems for review.

Even this small amount of data illustrates three different reasons why back translations may differ from the original text:

- Translator changed the meaning in the forward-translation.
- Translator changed the meaning in the back-translation.
- Literal back-translation of correct forward-translation appears to be error

The amount of data in this experiment is far too small to reach any definitive conclusions. It does, however, suggest that:

- Back-translations are valuable tools, but cannot replace editors.
- It may be essential for ICF authors to read the back-translations.
- A larger, more definitive, experiment would be worthwhile.

Back-translation increases the cost of translation by about 80%. A typical \$800 ICF translation charge would thus increase to about \$1,400. In addition, it takes time to make the necessary comparisons and correct errors. However, given the importance of accurate translations, the additional investment is more than justified.

Some Institutional Review Boards (IRBs) require back-translation of ICFs. For example:

“The Principal Investigator must translate the consent form if subjects expected to be enrolled are not fluent in written English. A completely translated copy of the informed consent and a complete back-translation done by two qualified translators must be submitted to the IRB before the translated ICF is approved.”<sup>3</sup>

(The ambiguity in this text reinforces the message that writing errors are easy to make. Does one translator do the forward-translation and another the back-translation, or do the two translators work together as a team on both translations?)

Because quality control personnel at translation companies are unlikely to speak every language their company translates, back-translation can also play an important role in identifying qualified translators.

**Table 1. Translations to Spanish**

<b>Original</b>	<b>Translation 1</b>	<b>Translation 2</b>	<b>Translation 2a (edited)</b>
You are being asked to participate in this study because you have been diagnosed with alopecia (hair loss) of the scalp. The purpose of this study is to determine if an experimental “study drug,” a patch containing capsaicin, is safe and effective when given to people with your condition. An experimental drug is one that has not received approval by the U.S. Food and	Se le ha pedido que participe en este estudio porque le han diagnosticado alopecia (pérdida del cabello) del cuero cabelludo. La finalidad de este estudio es determinar si el “fármaco experimental” de este estudio, un parche que contiene capsaicina, es seguro y eficaz cuando se administra a personas que padecen su afección. Fármaco experimental es aquel que aún no ha sido	Se lo invita a participar es este estudio por que se lo ha diagnosticado con alopecia (pérdida del cabello) en el cuero cabelludo. El propósito de este estudio es el de determinar si el “medicamento en estudio”, un parche de capsaicin, es seguro y eficaz cuando suministrado a personas con su condición. Un medicamento experimental es un medicamento que no ha recibido la aprobación	Se lo invita a participar en este estudio por que se le ha diagnosticado alopecia (pérdida del cabello) en el cuero cabelludo. El propósito de este estudio es el de determinar si el “medicamento en estudio”, un parche de capsaicin, es seguro y eficaz cuando se le administra a personas con su condición. Un medicamento experimental es un medicamento que no ha recibido la aprobación

Drug Administration (FDA).	aprobado por la Administración de Drogas y Alimentos de Estados Unidos (Food and Drug Administration, FDA).	de la Administración de Alimentos y Medicamentos de Estados Unidos (FDA, por sus siglas en inglés).	de la Administración de Alimentos y Medicamentos de Estados Unidos (FDA, por sus siglas en inglés).
Capsaicin is a man-made version of a peppery substance found in chili peppers. Low-concentration capsaicin creams and patches are available without prescription for controlling pain from arthritis (swelling of the joints), back pain and painful muscle soreness. However, it is unknown if the experimental patches containing 10 to 20 times higher concentrations of capsaicin will be helpful in reversing alopecia. It is also unknown if any hair growth that results from treatment will be temporary or permanent.	La capsaicina es una versión sintética de una sustancia picosa que se encuentra en los pimientos. Existen cremas y parches con bajas concentraciones de capsaicina, de venta sin receta, para el control del dolor causado por la artritis (inflamación de las articulaciones), dolor de espalda y fuerte dolor muscular. Sin embargo, no se sabe si los parches experimentales que contienen 10 a 20 veces la concentración de capsaicina serán útiles para revertir la alopecia. Tampoco se sabe si el crecimiento de cabello que pueda producirse a raíz del tratamiento será temporal o permanente.	Capsaicin es una versión fabricada por el hombre, de una sustancia picante que se encuentra en los chiles. Se pueden adquirir cremas y parches con baja concentración de capsaicin sin receta médica, para la artritis (inflamación de las articulaciones), el dolor de espalda y los dolores musculares. Sin embargo, se desconoce si los parches experimentales con concentraciones de capsaicin entre 10 y 20 veces mayores servirán para revertir la alopecia. Asimismo se desconoce si el crecimiento capilar que resulte del tratamiento será temporal o permanente.	Capsaicin es una versión, creada por el hombre, de una sustancia picante que se encuentra en los chiles. Se pueden adquirir cremas y parches con baja concentración de capsaicin sin receta médica para combatir el dolor causado por la artritis (inflamación de las articulaciones), el dolor de espalda y los dolores musculares. Sin embargo, se desconoce si los parches experimentales, que contienen concentraciones de capsaicin entre 10 y 20 veces mayores, servirán para revertir la alopecia. Asimismo se desconoce si el crecimiento capilar resultante del tratamiento será temporal o permanente.
If you qualify for the study, you will come in for two visits. At the first visit, we will measure your vital signs (blood pressure, heart rate, breathing rate and temperature), perform a physical exam, photograph your scalp, and take your medical history. We will collect a blood sample to measure the level of harontin in your blood. Harontin is a natural hormone associated with hair growth. We will collect	Si califica para el estudio, vendrá a dos consultas.  En la primera consulta se tomarán sus constantes vitales (presión arterial, frecuencia cardiaca, frecuencia respiratoria y temperatura), se le hará un examen médico, se tomará una fotografía de su cuero cabelludo y se obtendrá su historia clínica.  Obtendremos una muestra de su sangre para determinar el nivel de harontin. El harontin es una hormona natural	En el caso de que usted califique para participar en el estudio, deberá presentarse a dos visitas médicas. En la primera visita, mediremos sus señales vitales (presión arterial, ritmo cardiaco, ritmo respiratorio y temperatura), realizaremos un examen físico, tomaremos una fotografía de su cuero cabelludo y haremos una historia clínica. Haremos una extracción de sangre para medir el nivel de la harontonina en su sangre. La harontonina es una	En el caso de que usted cumpla con los requisitos para participar en el estudio, deberá presentarse a dos visitas médicas. En la primera visita, mediremos sus señales vitales (presión arterial, ritmo cardiaco, ritmo respiratorio y temperatura), realizaremos un examen físico, tomaremos una fotografía de su cuero cabelludo y redactaremos su historia clínica. Haremos una extracción de sangre para medir el nivel de harontonina en

approximately 2 tablespoons of blood. You will be asked to rate any discomfort or pain you have before, during and after the study patch application.	asociada con el crecimiento del cabello. Obtendremos aproximadamente 2 cucharadas de sangre. Le pediremos que nos diga cuál es el nivel de dolor que tiene, durante y después de la aplicación del parche del estudio.	hormona natural que se asocia con el crecimiento capilar. Le extraeremos aproximadamente 2 cucharadas de sangre. Se le pedirá que evalúe el nivel de molestia o dolor que siente antes, durante y después de la aplicación del parche en estudio.	su sangre. La harantonina es una hormona natural asociada al crecimiento capilar. Le extraeremos aproximadamente 2 cucharadas de sangre. Se le pedirá que evalúe el nivel de molestia o dolor que siente antes, durante y después de la aplicación del parche en estudio.
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**Table 2. Original and Back Translations**

<b>Original</b>	<b>Back Translation 1</b>	<b>Back Translation 2</b>	<b>Back Translation 2a (edited)</b>
You are being asked to participate in this study because you have been diagnosed with alopecia (hair loss) of the scalp. The purpose of this study is to determine if an experimental "study drug," a patch containing capsaicin, is safe and effective when given to people with your condition. An experimental drug is one that has not received approval by the U.S. Food and Drug Administration (FDA).	You have been asked to participate in the study because you have been diagnosed with alopecia (hair loss) of the scalp. The purpose of this study is to determine whether the "experimental blood" of the study, a patch which contains capsaicin, is safe and efficacious when administered to persons suffering from your condition. An experimental drug is one which has not been approved by the United States Food and Drug Administration (FDA).	You are invited to participate in this study because you have been diagnosed with alopecia (hair loss) on the scalp. The purpose of this study is to determine if the "medication under study", a capsaicin patch, is safe and effective when provided to persons with your condition. An experimental medication is one that has not received the approval of the Food and Drug Administration of the United States.	You are invited to participate in this study because you have been diagnosed with alopecia (hair loss) on the scalp. The purpose of this study is to determine if the "medication under study", a capsaicin patch, is safe and effective when administered to people with your condition. An experimental medication is a medication that has not received the approval of the Food and Drug Administration of the United States (FDA).
Capsaicin is a man-made version of a peppery substance found in chili peppers. Low-concentration capsaicin creams and patches are available without prescription for controlling pain from arthritis (swelling of the joints), back pain and painful muscle	Capsaicin is a synthetic version of a spicy substance which is to be found in hot peppers. There are creams and patches with low concentrations of capsaicin, which are sold without a prescription, for the control of pain caused by arthritis (joint	Capsaicin is manmade version of a spicy substance found in hot peppers. Creams and patches with a low concentration of capsaicin can be purchased without a medical prescription, for arthritis (swelling of the joints), back pain and muscle pain.	Capsaicin is a version of a spicy substance created by man that is found in chili peppers. Creams and patches with a low concentration of capsaicin can be purchased without a medical prescription, to fight off pain caused by arthritis (inflammation of the joints), back pain

<p>soreness. However, it is unknown if the experimental patches containing 10 to 20 times higher concentrations of capsaicin will be helpful in reversing alopecia. It is also unknown if any hair growth that results from treatment will be temporary or permanent.</p>	<p>inflammation), shoulder pain and <b>severe muscular pain</b>. However, it is not known whether the experimental patches, which contain 10 to 20 times the concentration of capsaicin, will be useful for reversing alopecia. Nor is it known whether the hair growth which may be produced as a result of the treatment will be temporary or permanent.</p>	<p>However, it is unknown if experimental patches with capsaicin concentrations 10 to 20 times stronger will serve to reverse alopecia. It is also unknown if the <b>capillary</b> growth resulting from treatment will be temporary or permanent.</p>	<p>and muscular pain. However, it is not known if the experimental patches, which contain concentrations 10 and 20 times higher of capsaicin, will help to reverse alopecia. Neither is it known if the <b>capillary</b> growth resulting from treatment will be temporary or permanent.</p>
<p>If you qualify for the study, you will come in for two visits. At the first visit, we will measure your vital signs (blood pressure, heart rate, breathing rate and temperature), perform a physical exam, photograph your scalp, and take your medical history. We will collect a blood sample to measure the level of harontin in your blood. Harontin is a natural hormone associated with hair growth. We will collect approximately 2 tablespoons of blood. You will be asked to rate any discomfort or pain you have before, during and after the study patch application.</p>	<p>If you qualify for the study, you will come to two <b>consultations</b>. At the first consultation, your vital signs will be taken (blood pressure, heart rate, respiration rate and temperature), you <b>will be subjected to a medical</b> examination, a photograph of your scalp will be taken and your clinical history will be recorded. We will take a sample of your blood in order to determine the level of harontin. Harontin is a natural hormone associated with hair growth. We will take approximately 2 <b>spoonfuls</b> of blood. We will ask you to tell us the <b>level of pain</b> you experience during and after the application of the study patch.</p>	<p>If you qualify to participate in the study, you shall come for two <b>medical</b> visits. At the first visit, we will measure your vital signs (blood pressure, heart rate, respiratory rate and temperature), perform a physical examination, take a photograph of your scalp and complete a medical history. We will take a blood sample to measure the level of <b>harontonina</b> in your blood. <b>Harontonina</b> is a natural hormone that is associated with <b>capillary</b> growth. We will take approximately 2 tablespoons of blood. You will be asked to evaluate the level of discomfort or pain that you feel before, during and after the patch under study is applied.</p>	<p>In the event that you meet the criteria for participating in this study, you shall go to two <b>medical</b> appointments. In the first appointment, we will measure your vital signs (blood pressure, heart rate, respiratory rate and temperature), perform a physical exam, take a photograph of your scalp and prepare your medical history. We will take a blood sample to measure the level of <b>harontonina</b> in your blood. <b>Harontonina</b> is a natural hormone associated with <b>capillary</b> growth. We will take approximately 2 tablespoons of blood. You will be asked to assess the level of discomfort <b>of</b> pain that you feel before, during and after applying the patch under study.</p>

**Table 3: Translation 2a Substantive Changes**

<b>Change</b>	<b>Comments</b>
<p>Changed "experimental 'study drug'" to "medication under study".</p>	<p>"Medication under study" does not fully communicate the concept of "experimental drug". The change was made in the forward-</p>

	translation.
Changed "hair" to "capillary.	"Capillary" in English means "a very small blood vessel." In Spanish, "capilar" not only means a very small blood vessel, but it also means "related to the hair." The forward-translation was correct.
Changed "visits" to "medical appointments".	Most clinical research is not "medical care". The subject may, for example, receive a placebo. Calling visits "medical appointments" may increase the subjects' therapeutic misconception. The change was made in the forward-translation.
Changed the term "harontin" to "harontina".	The change was made in the forward-translation. Translators could not find this term in any of the medical dictionaries, so they substituted it with a name that had a more Spanish flavor.
Changed "discomfort or pain" to "discomfort of pain"	The concept is lost that pain may be so minor as to be classified as mere discomfort. The forward-translation was correct; the change was made in the back-translation.

## References

1. 45 CFR 46.116
2. ICH Subpart B Section 50.20
3. Boston University Medical Center IRB Policies and Procedures last accessed 1/16/05 at [http://www.bumc.bu.edu/www/bumc/irb/Images/pp\\_infconsent.htm](http://www.bumc.bu.edu/www/bumc/irb/Images/pp_infconsent.htm)

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