TOOL 4

Creating a *Translation Brief* for: Informed Consent Forms

MORE THAN WORDS

What is a Translation Brief?

As described in *Developing a Translation Brief (Hablamos Juntos,* Tool #3), the translation brief enables translation requesters to share their understanding of the original English document, making the purpose and use of source text clear with detailed instructions for the intended translation product—so the requester and translator are, quite literally, on the same page from start to finish.

PURPOSE: To improve the quality of translated informed consent forms by providing guidance on the preparation and use of a translation brief. This guide illustrates how to develop a translation brief for the special case of the informed consent form.

NEED: Translation quality can be improved by stepping back and considering how texts achieve their communicative purpose as well as any special assumptions or cultural practices that may be embedded in the content. Because health care texts take many forms with defined communicative purposes (e.g., disease-specific educational handouts or booklets, marketing or health benefits brochures, registration forms), requesters need to understand the implications of culturally-determined conventions and writing styles associated with different text types. That is the purpose of this tool: to explore the unique origins, purposes, and attributes of informed consent forms in order to help translation teams make the choices that will lead to translations that achieve their communicative purpose (rather than, e.g., word-for-word translations).

SOURCES: Toward this end, Tool #4 summarizes the background information in Tool *#5*: *A Practical Guide to Informed Consent* and the ideas explained in Tool #3 to create a translation brief for translation of informed consent forms.

Hablamos Juntos
We speak together.

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Tool #4 synthesizes the concepts found in two other publications in the *More Than Words Toolkit Series* to illustrate how translation briefs can be created for informed consent forms—a specific source text type.

Who Should Use This Guide:

This guide is meant for requesters or individuals (or departments or organizations) responsible for initiating translations of informed consent forms. In some cases, it may be used by the original author(s) or the translator to initiate discussion with the person(s) requesting the translation.

How to Use This Tool:

Section 1: Understanding Informed Consent Forms

Start by reading Section 1 which describes the informed consent form, its medical and legal attributes and the special challenges this unique text type presents to health organizations and for producing translations.

Section 2: How to Develop Translation Brief for Informed Consent Forms

Next, examine the step-by-step instructions and examples in Section 2 to understand how one should develop a translation brief for consent forms. This goes through the steps of developing a translation brief, applied to the special case of the informed consent form. This includes gathering information about the purpose and unique function of consent forms, evaluating the quality of source text and comparing and contrasting the source and target audiences to develop instructions for translating the consent form.

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Understanding Informed Consent Forms

The informed consent form formalizes communication between a patient and physician and concludes with the patient's informed authorization to undergo a medical intervention. For medical, ethical and legal reasons, patients must be given enough information to be fully informed before deciding to undergo a major treatment and their informed consent must be verified in writing. In most U.S. institutions today, a signature on a consent form is required for surgery, anesthesia and other invasive or complex medical or radiologic procedures (although the exact requirements vary from state to state and institution to institution). A signed consent form attests to an exchange of information that represents an informed consent. The informed consent form as a text type is unique to Western medicine and does not always have an equivalent in other languages and cultures, which is why translations of such documents is difficult yet very important.

> "The informed consent form formalizes communication between a patient and physician and concludes with the patient's informed authorization to undergo a medical intervention."

The Fundamental Problem: Informed Consent is Difficult to Do Well in English

Unfortunately, even after signing a consent form, many patients still do not understand all of the risks and benefits of their proposed treatment choices. The Joint Commission, the accreditation agency for most health facilities in the U.S. has found that among patients who sign a consent form, 60 to 70 percent do not read or understand the information contained on the form. Even many native speakers of English struggle to make sense of the medical and legal content of consent forms. This gap between the ideal function of the informed consent form process and everyday reality increases the risk for medical errors, safety breakdowns and malpractice claims. Foreign language and cultural differences add yet another hurdle to an already difficult task.

Informed Consent: From Ideal… to Reality… to Practical Solutions

Required Elements or Goals

Signed form indicating patient wants treatment and understands:

- Diagnosis/condition
- Nature/purpose of treatment
- Risks/benefits of treatment
- Alternatives
- Risks/benefits of alternatives
- Risks/benefits of no treatment plus doctor statement that the patient understands and statement (as needed) that an interpreter provided services

Barriers

Patient factors:

- Low health care literacy
- Limited English proficiency (LEP)
- Intimidation/stress
- Confusion about the consent process

Provider factors:

- Time limitations
- Complex forms/language
- Lack of interpreters and/or translated forms
- Wrong assumptions re: patient comprehension

Best Practices

Form Simplicity:

- Design/layout
- Word choice
- Readability

Message Tailoring:

- Discuss with patient
- Allow time for Q+A
- Use "teach back" to ensure patient comprehension
- Use the language of the patient

Several best practices have been suggested to guide communication between patients and physicians to improve the effectiveness of obtaining informed consent. Presumably, these best practices are also adopted for limited English proficiency (LEP) patients, although preparing a translation brief for an informed consent form project is an opportunity to determine how well this ideal holds up. Some health care organizations and systems, in an attempt to service the needs of low literacy populations, have also successfully applied standards for format and readability of their consent forms. The procedural consent forms from the Queensland Government of Australia are considered a model of simplicity, consistency and effectiveness. They even go one step further by anticipating cross-cultural encounters and the use of interpreters. On these forms, interpreters must also sign the consent form when they are involved.

Research done by *Hablamos Juntos* and others indicate that most English consent forms today are still too complex and legalistic or (as with generic fill-in-the-blank forms) too non-specific. The challenge of producing easier-to-read informed consent forms in English and ideas for practical solutions are the focus of *A Practical Guide to Informed Consent* – Tool #5 of the *More Than Words Toolkit Series* and a companion to this guide.

The Need for Translated Consent Forms

The inability to speak English well is widely recognized as a major cause of failed communication in obtaining informed consent and in other health care communications. This explains why many health care organizations employ interpreters to enable discussion of treatment options and/or to sight translate English consent forms (sight translation is verbal translation or oral interpretation of a written text, often without any preparation time). In fact, a variety of state laws, federal policies (e.g., Title VI of the Civil Rights Act of 1964, Office of Minority Health CLAS standards) and accreditation standards (e.g., The Joint Commission, Health Insurance Portability and Accountability Act, National Committee for Quality Assurance) now require health care organizations to ensure all important documents for LEP patients are culturally and linguistically appropriate. More specifically, the U.S. government in Executive Order 13166 requires that informed consent forms be translated into languages spoken by at least 5% or 1,000 of a provider's patients, whichever is less/fewer.

"Research done by *Hablamos Juntos* and others indicate that most English consent forms today are still too complex and legalistic or (as with generic fill-in-the-blank forms) too non-specific."

Within the health care industry, untrained or inadequately-prepared translators are a primary source of health materials translations. Working with health care organizations in 10 states, *Hablamos Juntos* has found that producing non-English informed consent forms is typically a struggle for health care organizations. As with the English versions of these forms, there is a gap between the ideal and reality.

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Queensland Informed Consent Form Elements

- Interpreter/Cultural Needs
- Condition and Procedure
- Anesthesia
- General Risks of Procedure
- Risks of this Procedure
- Significant Risks and Relevant Treatment Option

Signatures Required of the:

- Patient
- Interpreter—if one is involved
- Doctor performing the procedure

In some cases, the problem can be traced directly to the poor quality of the English version. However, even when the source consent form is exemplary, the translated versions often are difficult to read, even for target audiences with high literacy skills. These difficulties may involve not only practical limitations in budgets and poor translation planning and review, but also technical challenges such as a scarcity of staff experienced in commissioning translations. Tool #3 discusses common obstacles requesters face, including the challenge of distinguishing high-quality translations from low-quality translations. As a result, low-quality translations are common: they not only contain errors in grammar, spelling and vocabulary, but also have problems of over-literalism (i.e., strict word-for-word translation) that obscure the original intent and neglects cultural nuance. Current quality measures such as back-translation into English are not effective as the **Example of Word-for-Word Translation** shows. What may look correct in English belies awkward, unnatural translation in a target language.

Example of Word-for-Word Translation

Source:	**You CANNOT get TB from…**
Translation:	你 不能 感染 结核病 从 …
Back translation:	**You cannot get TB from**
Result:	**Very awkward Chinese, but difficult to appreciate for those unfamiliar with the language**

(Refugee Health Information Network, 2009)

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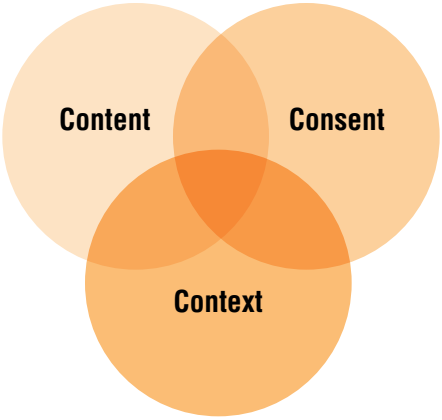

…Concepts that overlap and must be considered together

The New Challenge for Translators: Context and Content in Informed Consent

Assuming for a moment the availability of a high-quality source consent text and the involvement of competent translation professionals, what else would be needed to produce a high-quality translation of an informed consent form? At *Hablamos Juntos*, we believe the extra challenge involves disabusing the commonly-held view that the objective of a translation project is to produce an equivalent target text. The notion of equivalence is a vague and often controversial term subject to numerous interpretations. Every language is a unique form of communication shaped by underlying cultural practices, values and beliefs. The conventions and elements of a text (e.g., title, tone, writing voice) are dictated by cultural norms associated with the form and purpose of communication. This is why word-for-word renditions of English are often not possible and why approximations of an English text, or faithfulness to the intended meaning of a source text, are more appropriate.

Example of Meaning-for-Meaning Translation[3]

Source:	**Cool, pale skin, cold hands and feet**
Translation:	皮肤　苍白发凉，手　足　冰 冷
Meaning translation:	**Skin [is] pale cool hands feet ice cold**

The change of the grammatical structure in the meaning-for-meaning translation makes for more natural and idiomatically correct Chinese without losing the intended meaning. The difference is significant to the Chinese reader.

(Health Information Translations, 2009)

Without an understanding of a source texts use, purpose and goal, even translations produced by well-trained translators may not be useful to target audience. The consequences of low-quality translations can be dire for LEP patients who are on the cusp of making important, often life-changing, health care decisions. Some translation guidelines now emphasize that translations should be measured against criteria agreed upon in advance. The broader purpose and the unstated assumptions (often culturally determined) embedded in a specific type of text need to be identified and the implications for a target text need to be considered (ISO 9000:2000, ASTM International F-2575-06 2006). With this approach, the scope of translation requires looking beyond a faithful word-for-word translation. Explicitly setting criteria is essential to permitting translators to navigate within a specified degree of variation and subjectivity. Informed consent forms have legally-defined requirements often not stated on the form itself. Translators need specific guidance to pursue a meaning-for-meaning translation, so the contextual elements that are deeply embedded within the informed consent form need to be made clear. Without this type of guidance, the outcome can be translations that are even less understandable in the target language.

As discussed next, the translation brief is a tool designed to convey such guidance.

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How to Develop Translation Briefs for Informed Consent Forms

In this guide, the key steps for creating a translation brief for informed consent forms are summarized. These instructions use the framework provided in *Developing a Translation Brief (*Tool #3), with a focus specifically on the informed consent form. These four steps provide an organized means of thinking about a consent form translation project, help one develop clear specifications for a translator, and in some cases, cause one to rethink the project all together.

STEP 1: Gather information about the **function, overall purpose and end use** of the source informed consent form. Learn about the source form and how it is used with the source audience.

STEP 2: Evaluate the quality of the source form to make a **GO / NO-GO decision**. Poor-quality source texts hinder the production of useful translations.

STEP 3: Compare and contrast the relevant aspects of the source and target audiences to identify implications for the target form. Analyze the content of the source form to identify any evidence of **source culture bias** that will need to be replaced by target culture conventions, as well as translation challenges that will need to be overcome, including production challenges.

STEP 4: Summarize **specific needs and special requirements** for the translator. These specifications will become the benchmarks to assess the quality of a translation product.

> **Preparing a translation brief, closely analyzing the source text, and comparing and contrasting source and target audiences can help identity potential roadblocks if the source consent form does not represent a good starting point.**

When developing a translation brief for an informed consent form, two concerns unique to this text type need to be considered at every stage of the process. First, because of the potentially high-stake legal and clinical consequences associated with the use of an informed consent form, requesters need to recognize that unlike other text types (e.g., health education materials), there may not be much flexibility in what information is presented. Understanding the intended meaning is critical to creating translations that meet their intended objective of informed consent. Second, for precisely the same reasons just cited, it is crucial that translation products support informed decision-making by the patient as well as satisfy physician and institutional responsibility for full disclosure. To this end, translated consent forms must capture the full original intent of the source text in a way that target audiences can understand.

A fundamental goal of Tool #4 is to make sure that the communicative goal of informed consent forms are met by all translations. Preparing a translation brief, closely analyzing the source text, and comparing and contrasting source and target audiences can help identity potential roadblocks if the source consent form does not represent a good starting point. Informed consent forms written in heavily-legal or medical terms, even if translated by translators knowledgeable in the legal or medical fields, may not be easily understood by target audiences. Requesters can weigh this possible result to make a decision about whether to proceed with a translation project or to explore alternatives such as improving the source informed consent form or developing capacity for sight translation of consent forms for LEP patients.

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Step 1: Gather Information about the Source Informed Consent Form, Its Overall Purpose and Use

The essence of a translation brief is to describe the purpose and use of a text by making clear the function of the text, the intended audience and how the text is introduced to its reader. The **text function, overall purpose and use** of informed consent forms are established in law and represent the culmination of a process of communication between a patient and physician, leading to the patient's authorization to undergo a specific medical intervention (American Medical Association, 1998). The content of informed consent forms (explaining the condition and proposed treatment, general risks and benefits of the procedure, and treatment alternatives) pose significant challenges for translation, particularly for target audiences where the concepts embedded in the informed consent process may not exist.

Before proceeding with a full evaluation of the source informed consent form, ensure that the document is indeed an informed consent form (the "text type") and that its purpose is to document the patient's approval to move ahead with a test, procedure, surgery or other significant medical event.

What is the purpose and use of an informed consent form?

For both ethical and legal reasons, patients must be given enough information to become fully informed before deciding to undergo a major treatment. The informed consent form is designed to document essential information that must be given to a patient in making this decision. The content represents carefully-considered wording approved by the physicians performing these services, legal counsel and risk managers. Whatever the reason, the consequences of ill-informed consent can be serious. Beyond the fundamental breach of ethical and legal duties to inform the patient, there is also the increased potential for medical errors and malpractice claims.

When a request for translation is first received, the source informed consent form should be evaluated on a global level to understand its exact purpose. In this case, informed consent is an ethical concept that all patients should understand and agree to the potential consequences of their care. This principle has become codified in law and in daily practice at every U.S. medical institution. One of the earliest legal precedents in this area was established in 1914 when a physician removed a tumor from the abdomen of a patient who had consented to only a diagnostic procedure (Schloendorff vs. Society of New York Hospital). The judge ruled that the physician was liable for battery because he violated an "individual's fundamental right to decide what is being done with his or her body" (Edwards, Lilford, Thornton and Hewison, 2005). The first case actually defining the elements of informed consent occurred in the late 1950s and involved a question of potential negligence and whether a patient was given sufficient information to make a decision. The case law and rules pertaining to informed consent have changed over the years and all 50 states now have legislation that requires some level of informed consent

Pre-Translation Analysis

For most experienced translators, pre-translation analysis is often second nature and a highly-refined analytical process of studying the source language text. Good translators also know that the purpose and use of a text in its natural environment are essential to understand before undertaking a translation. The translation brief makes these critical elements clear, eliminating guess work, incomplete information or incorrect assumptions.

(Pape, 1997). Although the details of these laws vary from state to state, the bottom line is that failure to obtain informed consent renders U.S. physicians liable for negligence or battery and constitutes medical malpractice (Pizzi, Goldfarb and Nash, 2001). Exceptions are made for emergencies or legally-adjudicated mental incompetency or physical incapacity circumstances. The burden on the individual physician is extended to facilities that support medical care or procedures requiring informed consent. Hospitals and other health facilities accredited by The Joint Commission must establish and follow policies that define which procedures or care, treatment, or services require informed consent (Joint Commission R1 2.40, 2005).

Use the three-column table described in Tool #3 to capture details of the source consent form to be translated. In Step 1, the aim is to make clear why a text was written and how it is used. The focus should be on the source text and its original audience. See Tool #5 for a discussion of why informed consent forms often fail to achieve their stated purpose with English-speaking patients.

	Source Text	**Target Text**
	English	(Insert Language)
Function	What is the intended purpose/use of the text? It formalizes the communication between a patient and the physician who is obligated to explain the condition and proposed treatment, general risks and benefits of the procedure and treatment alternatives.	
Audience	Who is the recipient of the source text? Are there common patient characteristics (e.g., performed only on women) or pre-existing features (e.g., chronic illness, sudden injury)? Patients identified by their physician as having a defined condition.	
Time of Reception	When and by what means is the source text given to a patient and by whom? Is key information explained? Patients sign an informed consent form on the day of surgery as part of the admissions process (or a relative's signature is required because the patient is unable to sign the form).	
Place of Reception	Where does the reader encounter the text? Is the text given to the reader, picked up in the doctor's office, etc.? It is given at the surgery center by the admissions nurse.	
Purpose	Why was the source text written? Is there a desired reader response? It formally documents that a patient understands the treatment being proposed, the potential consequences of his or her care and that the patient consents to the treatment.	

It is the formality and finality of obtaining a signature that distinguishes an informed consent form from other routine patient education that occurs in nearly every clinical encounter. In most institutions, this formal process of requiring a signature is reserved for surgery, anesthesia and other invasive or complex medical or radiologic procedures. Laws vary from state to state about when and how formal informed consent must be provided, but national standards do exist.

For the informed consent form, recipients are identified by their physician based on predetermined medical criteria. The medical problem and the implications of the required care are discussed by the physician and the patient. It is necessary to consider whether there are patient characteristics (e.g., physical limitations, emotional state, literacy) that may influence how the consent form is used. In-depth examination of cultural and language differences between the source and target audiences should take place in Step 3.

Give attention to practical considerations related to the time and place where the informed consent form is introduced to the source audience. It is necessary to describe how the text is introduced to the patient and the parties involved. Although all informed consent forms share common elements, how the form is presented to the source or target audience may vary.

Step 2: Evaluate the Quality of the Source Informed Consent Form

Before commencing a translation project, consider the quality of the source informed consent form very closely. Decide whether it represents a good starting point in terms of written quality and how likely its English audiences are to find it understandable. The result of this "assessment" will help determine the next steps. Also consider the overall purpose and audience for the new target informed consent form and ask whether a translated version of the source form will achieve the desired communicative purpose, namely informed consent.

Quality of the Source Consent Form

With purpose, audience and context in mind, take a critical look at the English source text. In particular, ask the following questions:

- Is the informed consent form clear, easy to read and understand?
- Is it accurate and current?

In particular, look for these key features in the source informed consent form:

- All required elements of informed consent? (See checklist)
- Accurate and current?
- Plain language (easy-to-read, simple, clear and free of technical or legal jargon)?

- Short sentences in direct, active voice? Grammatically correct?
- Organized flow of ideas, with clear layout, design and text chunking/paragraphing?
- Specialized terms or concepts clearly explained?

The results of this "assessment" will help determine the next steps.

Make GO / NO-GO Decision

GO! If, in your judgment, the answers to the above questions are "yes," the source text appears suitable for translation. Proceed to Step 3.

STOP! If, on the other hand, the answer to any of the questions is "no," consider alternatives to translating the content, including improving the source text, finding a new source text or developing non-literacy-based alternatives such as pictograms or audio or video materials.

Checklist for the Ideal Informed Consent Form

- The diagnosis, if known
- The name, nature and purpose of the proposed treatment or procedure
- The risks and benefits of proposed treatment or procedures
- Alternative procedures and treatments
- The risks and benefits of alternatives
- The patient's right to refuse treatment or procedure as an alternative
- The risks and benefits of not receiving treatments or undergoing procedures
- Name and signature of the patient or legal guardian
- Name of the hospital
- Name of all practitioners performing the procedure and individual significant tasks if more than one practitioner
- Date and time consent is obtained
- Statement that procedure was explained to patient or guardian
- Signature of professional witnessing the informed consent
- Name, signature, and statement from person or interpreter who explained the procedure to the patient or guardian in a way they could understand

Source: AMA Standards for Informed Consent (1998), Federal Code Title 42, Joint Commission National Patient Safety Goals (2008)

Step 3: Compare and Assess Source and Target Text Differences

Specifically, analyze the source document by visualizing the planned target document in terms of how well it helps achieve the objective of informed consent. Although the physician ultimately is held legally responsible for administering the informed consent process, the reality is that various members of the medical team take part in the information giving process and obtain the required signature(s). Focusing on the most likely scenario will help envision how informed consent happens and how the form will be used to support the informing process. For example, the staff members who may be directly involved in educating and informing the patient include doctors (generalists, specialists, or hospitalists), nurses, nurse practitioners, and laboratory technicians. In some cases, the doctor will be the patient's primary care physician or specialist; in others, he or she will be a stranger. Oftentimes, a specialist (perhaps an anesthesiologist) may arrive to explain specific details, answer questions, or hand out printed educational information. Again, imagining the whole scene can only improve the translator's understanding of the role to be played by the translation. With that likely scenario in mind, next consider how the scene may change for the target audience.

	Source Text	**Target Text**
	English	(Insert Language)
Function	What is the intended purpose and use of the informed consent form? It formalizes the communication between a patient and the physician who is obligated to explain the condition and proposed treatment, general risks and benefits of the procedure and treatment alternatives.	Will the target text be used in the same way? Same use except patient will receive required information from his or her doctor through a professional or ad hoc interpreter or bilingual staff member. List any other adaptation to the process (e.g., anesthesiologist speaks to patient in the office during a scheduled appointment rather than on the day of surgery).

The function and purpose of the informed consent form is fundamentally the same for both the source and target audience. However, language barriers change the way the target audience and the informed consent form interact. With the target audience in mind, consider whether translation of the consent form is desirable given the potential for highly technical content and medical terminology. Also consider whether the underlying assumptions or values embedded in the source text are familiar to, or shared by, the target audience. Asking basic questions to consider how the informed consent is likely to be used with the target audience, and comparing and contrasting this with how the source text is used with the source audience, helps raise awareness of new requirements that cultural

and language differences may impose. This exercise enables requesters not only to identify the requirements of a translated text, but also to plan how practices associated with the source text will need to be adapted for the target audience.

	Source Text	Target Text
	English	(Insert Language)
Audience (Patient)	Who is the recipient of the source text? Patients identified by their physician as having a defined condition Common beliefs, values, practices or demographic features Common features associated with the condition	Are the characteristics of the target audience similar or dissimilar to the source audience? The medical treatment indicated requires informed consent Demographic or other features are relevant or not

A wide range of target audience beliefs and assumptions (e.g., health, values, authority, permissions, signatures, the law, fate) may impact the informed consent process. Talk with direct line staff to learn what is already known or observed about the target audience, particularly experiences involving informed consent. In this process, listen for challenges presented by the subject matter or the ideas reflected in the content. Look for core assumptions about what the audience is expected to know or believe as well as knowledge from past experience with signing consent forms or information given through other sources. Learn about experiences obtaining signatures on consent forms and basic practices such as how the concepts of informed consent are explained. While the concept of informed consent is embedded in medical practice, many LEP patients and even many English-speaking patients may not be familiar with this practice. The process of comparing source and target audiences helps identify differences that will need to be addressed either in practice or in the translation product.

"The process of comparing source and target audiences helps identify differences that will need to be addressed either in practice or in the translation product."

Identifying the Cultural Implications of Core Assumptions

Preparing a translation brief may help raise early fundamental questions about whether a translation is the best strategy for meeting the particular information needs of a targeted LEP population. Basic concepts used in consent forms (e.g., assessing risk, understanding probability estimates and approaches to decision-making) may not be meaningful to target audiences. New materials may be needed to explain unfamiliar concepts, or brief explanations included in the translations. Distrust, fear or conflict with one or more deeply-held beliefs may run counter to either the whole concept of informed consent or to any aspect of a specific procedure or treatment. Conflicting cultural practices may essentially

rule out the procedure/treatment completely (e.g., use of blood products), rendering translations moot and requiring new approaches to bridge these likely differences.

At this stage in preparing the translation brief, identifying these challenges or barriers early and talking with interpreters or health care professionals from the same target culture may provide opportunities to anticipate how standard practices may need to be adapted before resources are expended on a translation that may not achieve the desired outcomes. In addition, how these issues are addressed (e.g., adopting new practices for obtaining consent, creating supplemental target text or audio or visual tools) may require explicit guidance from established informed consent form approval bodies. For example, the underlying assumption of informed consent is the patients right to refuse any treatment: for some target audiences, the right to refuse treatment or to request a different facility or physician may need to be made explicit and with assurances of non-retaliation. Through this process, the commissioned consent form may end up being significantly different than the source text.

Understanding the most likely venue and situational features of the informed consent process will help the translator further hone the translation. In some cases, the translated consent form may not be used in the same setting as the English form. In addition, assumptions regarding the availability of language support will be a factor in shaping the final translation. Even if the timing and location of informed consent are identical for the source and target audiences, awareness of the form's intended use (which is most often not explicit in the source document) may inform and improve the translation.

	Source Text	**Target Text**
	English	(Insert Language)
Time of Reception	When, how and by what means is the source text given to the patient and by whom? Key information is explained, patients sign an informed consent form on the day of surgery as part of the admissions process (or a relative's signature is required if the patient is unable to sign the form).	Will the target text be given in the same way, and by whom? Patients sign the informed consent form in the emergency room with an interpreter present two weeks before the surgery.

Making note of where and when the patient will receive the form may uncover the need for more information, or for highly-specific information, on the translated consent form. Consider where the organization using the form is located (e.g., country, state, county, city) and where the form will likely be distributed (e.g., clinic exam room, laboratory, emergency room, waiting area, front desk, hospital room).

	***Source* Text**	**Target Text**
	English	(Insert Language)
Place of Reception	Where does the reader encounter the text? Is the text given or picked up? Patients are given the form at the surgery center by the admissions nurse.	Will the target audience encounter the text in the same way? Because translators are stationed in the emergency department, the triage room or nurses station.

The informed consent form may be presented to the patient by the physician performing the procedure or by attending support staff, in the physician's office or at a surgery center. If the form is presented in a physician's office or by the physician, it may be more easily understood in the context of the conversations that have occurred between the physician and the patient. Informed consent forms presented for signature on the day of the procedure by attending support staff may not as easily be connected to conversations that have taken place with the physician. Moreover, language barriers may require the involvement of interpreters or bilingual staff stepping into an assignment outside their daily responsibilities. Understanding the venue surrounding the target text's delivery/receipt will help identify process differences and provide the translator with an understanding of contextual influences contributing to how target audiences understand what they are signing.

> **"Understanding the venue surrounding the target text's delivery/receipt will help identify process differences and provide the translator with an understanding of contextual influences contributing to how target audiences understand what they are signing."**

The lag time between the physician's explanation of the procedure and the request for signature on the informed consent form needs to be understood by the translator. Is the informed consent form dependent on the patient-doctor discussion solely or are surgery center staff trained to repeat, reinforce and seek verification that a patient understands the content of the consent form? Finding out exactly when the form will be used may open the door to assumptions embedded in how the information is organized. For example, the amount of time the patient and his/her family have to review the informed consent form may affect cultural practices (e.g., collective cultures where hierarchy or group decisions are important). In some situations, the urgency of treatment may supersede and limit review time; all the more reason to consider and plan for the cultural implications of these requirements. In other cases (e.g., elective procedures), there may be time for the patient to take the form home to engage in discussion and approval as required by their community and culture. This is important to know as it may affect how the translation is approached.

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	Source Text	Target Text
	English	(Insert Language)
Purpose	When is the source text given to a patient, and by whom? How is the text given? Is key information explained? It formally documents that a patient understands the treatment proposed, the potential consequences of his or her care and that the patient knowingly consents to treatment.	Why is it being translated? Is the desired target reader response the same for the source audience? The requirement to formally document the patient's understanding of the treatment proposed, the potential consequences of their care applies to all patients.

The purpose of the informed consent form is to document a patient's agreement to undergo a specific medical intervention. In obtaining a signature on the informed consent form, there are ethical and legal reasons to ensure that the signatory has been given enough information to fully understand the implications of his or her decision. The desired outcome is the same for both the source and target texts. For this reason, it is important to make clear whether the translated version is signed and used for the medical record or whether a signature is required on the source informed consent form as well. This is an opportunity for requesters to consider whether a notation should be made on the target text to be sure the patient understands this practice.

Going beyond the informed consent form, other important considerations for both source and target audiences may include low health care literacy, limited English proficiency, confusion about the purpose of the informed consent process, a feeling of intimidation, and stress or time pressure. Other poorly-documented human factors that may negatively influence the patient's comprehension of medical information include memory and ability to recall, education level, and the timing of the informed consent session. Finally, other factors associated with poor-quality informed consent forms are overly-complex or generalized written materials, limited or no availability to interpreters, erroneous assumptions about patient comprehension and under-involvement of the physician responsible for assuring informed consent.

"The process of preparing translation briefs is also an opportunity to examine the quality of the source consent forms and to consider standardizing these texts for use with a diverse group of patients."

Once the first translation brief for informed consent forms is prepared, it can serve as a prototype for other consent form translation projects. The process of preparing translation briefs is also an opportunity to examine the quality of the source consent forms and to consider standardizing these texts for use with a diverse group of patients. The process of identifying source and target language differences strengthens the adoption of effective translation practices for informed consent forms, including establishing conventions or glossaries for consistently translating uniquely American health terms not common to other languages. In addition, each consent form project should be seen as an opportunity

to incorporate the lessons learned from past projects and to learn from actual experience using the translated consent forms in practice. In this regard, the translation brief encourages adoption of the basic quality improvement practices needed to continuously improve the quality of translated materials as well as meeting the communication needs of LEP patients.

An examination of core assumptions underlying the proposed text can help identify cultural- or language-related challenges and enable organizations to anticipate and prepare to meet the communication needs of their LEP population. If the proposed translation appears feasible, then proceed to Step 4.

Step 4: Summarize Specific Needs and Special Requirements of the Translator

In Step 4, a discussion or meeting between the requester and translator or project manager is recommended to review project goals, identify challenges and formalize project requirements.

The objective of Step 4 is to finalize instructions for the production of a translation that best represents the original goal(s) and intended purpose(s) of the source text. This step involves a preliminary discussion with the translator or project manager before translation instructions are finalized.

Meeting with the Translator is Ideal

A meeting or discussion between the requester and translator is highly recommended before finalizing the translation brief. How LEP patients receive information about the procedure they are consenting to, whether interpreters are available to assist with communication between the patient and medical professionals and whether the translated form should be used in conjunction with the English version are all matters that should be discussed with the translator. Also discuss with the translator, the profile of the typical target audience and past experience with achieving informed consent. This will provide an opportunity to share background analysis undertaken in Step 3 and engage the translator

TOOL 4

The Brief as Action Plan

The final version of the translation brief should represent a mutually-agreed-upon plan of action. A meeting or discussion between the requestor and the translator or project manager is highly recommended to review the draft translation brief before finalization. This provides an opportunity for a review of key findings (especially the goal/purpose of the informed consent), as well as the chance to ask questions, provide answers, and conduct further analysis and brainstorming. This interaction will be more productive if both parties have had a chance to review the source document and the draft translation brief before the meeting. After revising and finalizing the content, the brief will serve as the main guidance for the translation and criteria for evaluation.

in setting benchmarks for a quality translation product. Ideally, the challenges identified from comparing source and target audience differences are discussed and approaches to meeting the function and purpose of a consent form are established. This interaction will be more productive if both parties have had a chance to review the source text and a draft of the translation brief ahead of time.

During the discussion, the translator should identify areas of the source culture that may need to be adapted and suggest an approach that will ensure the needs of the target audience are met. Consideration should also be given to signature lines and related permission forms (e.g., HIPAA required) for the patient's approval during the decision-making process. On a broader level, agreement should be reached on the amount of literal translation expected, or conversely, the degree of non-literal meaning-for-meaning translation that is acceptable given the function and constraints of the consent form. In other words, how much latitude can the translators have in approximating content so that they can convey the intended meaning of the source form?

An Action Plan for Moving Ahead

In preparing translation instructions, it is important that requesters be very clear about specific wording or legal or medical content that must be retained and note where the translator may use more appropriate analogies or references. Provide available background on concepts, words or descriptions in the informed consent form that have presented challenges when sight translated by an interpreter. It is especially critical that the final brief provide the translator with very clear directions about what is expected and what is allowable in the finished product. Unlike health care education materials, informed consent forms may not permit much flexibility in what information is presented. However, as emphasized throughout this guide, translated consent forms must fully convey intended messages and the patient must understand what they are signing. After agreement is reached, the brief becomes the main source of guidance for the translation and criteria for evaluation.

Based on the detailed guidance found in the completed translation brief, move ahead with the meaning-for-meaning translation of the informed consent form.

During translation, use the brief to facilitate communication and evaluate progress. After completion of a draft translation, use the translation quality assessment tool to evaluate translation quality and determine whether the final product complies with project requirements as specified in the translation brief.

The translation brief can also be used by the translator as a reminder sheet when questions arise during the course of the translation. After delivery of the draft translation, for the requester, it can serve as a checklist to confirm that the translated text accurately conveys the intended goal(s) and purpose(s) and is appropriately targeted for the intended audience/patient and setting/context.

A Production of *Hablamos Juntos*

Since 2001, *Hablamos Juntos* ("We Speak Together"), a Robert Wood Johnson Foundation-funded national initiative, has been studying language barriers in health care for patients who speak or understand little or no English. In our years of work, the fundamental lesson we have learned is that communicating across languages and cultures involves much more than words. It requires recognition that the meanings of ideas and words are conveyed and extracted through the cultural lenses of the interlocutors. Attention to these differences is essential to effective communication, whether in writing via translation or speaking via interpretation.

The *Hablamos Juntos More Than Words Toolkit Series* brings together lessons learned from eight years of working with nationally-recognized health leaders and language experts and original research on translation quality. It has been made possible through the contributions of many around the country, including language faculty, researchers, practicing interpreters and translators and health care professionals dedicated to providing safe and quality health care to our diverse nation. Among those requiring special mention for the production of Tool #4 are Sonia Colina, Aracely Rosales and several translators and language professionals who reviewed and commented on earlier drafts.

For more information about *Hablamos Juntos* or to download the entire *More Than Words Toolkit Series,* visit www.HablamosJuntos.org.

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