Policy CON-101 Requirement for Long Form Translation Following Use of the Short Form

Policy Update: Effective January 31, 2025

Guidance and FAQs

This document reflects the current DF/HCC guidance around this policy requirement and frequently asked questions. Please note that this is general guidance, and the answers may vary or differ depending on the specific scenarios.

Effective January 31, 2025, the following requirement to DF/HCC policy CON-101: Obtaining Informed Consent from Non-English Speakers was implemented:

> 5.2.8. When a short form is used to consent a participant, the investigator must then also obtain a translated copy of the IRB-approved English version of the long form consent document in the language of the participant, which should be done promptly following the use of the short form.
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> 5.2.8.1. The translated full consent form must be submitted to the IRB for approval, in accordance with section 5.1.3.
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> 5.2.8.2. Once approved, the translated full consent form must be provided to the participant (or LAR), and it must be documented that this has occurred.

Why are modifications to this policy requirement needed?

DF/HCC leadership has determined that DF/HCC policy should be updated at this time to align with the clear FDA and DHHS guidance around this topic. Providing participants with a full consent document in a language they understand is important to the informed consent process for multiple reasons:

- **Expectation of Future and Ongoing Consent Process for Non-English Speakers in that Particular Language:** The regulatory guidance is clear: the use of a short form should only be used as a tool when a non-English speaker of a particular language is unexpected. The short form should not be used routinely. The guidance clearly interprets the previous (initial) need for a short form in a particular language is an indicator that obtaining consent from future participants in that language is no longer unexpected. Further, the currently enrolled participant may be expected to require future notification of new risk, and potentially reconsent. A fully translated consent document should be available for use during the ongoing consent process throughout the life of the study.
- **Participant Understanding and Autonomy:** The primary goal of informed consent is to ensure that patients fully understand the nature, benefits, risks, and alternatives of a clinical trial or medical procedure. Providing a translated long form ensures that non-English speaking patients have access to the same detailed information as English-speaking patients, thereby supporting their autonomy and ability to make informed decisions.
- **Ethical Standards:** Translating and providing the long form consent document aligns with ethical standards in research and healthcare, promoting equity and respect for all participants regardless of their language proficiency. It demonstrates a commitment to ethical principles such as justice and respect for persons.
- **Risk Mitigation:** Properly documenting informed consent through translated materials helps mitigate risks associated with misunderstandings or miscommunications. This can protect both the patient and the institution from potential disputes or claims of inadequate disclosure.
- **Enhancing Trust:** Providing comprehensive information in a patient's native language can enhance trust between the patient and the healthcare provider or research team. It shows respect for the patient's cultural and linguistic needs, which can improve patient satisfaction and engagement.
- **Quality of Data:** Ensuring that all participants have a clear understanding of the study or procedure helps maintain the quality and reliability of the data collected. Participants who are fully informed are more likely to adhere to study protocols and provide accurate data.

What do the regulations say?

We encourage research personnel to review in full the FDA guidance and DHHS OHRP guidance around the process of obtaining informed consent from non-English speaking participants. Below are highlighted excerpts specific to this updated DF/HCC requirement:

DHHS - FDA Guidance: Informed Consent (2023)

"The information given to the prospective subject, which includes both information provided orally during the consent discussion and written information in the consent form, must be in language understandable to the prospective subject or LAR (21 CFR 50.20). "Understandable" means the information presented to prospective subject is in a language and at a level the subjects can comprehend (including an explanation of scientific and medical terms) …

…After the subject has been enrolled in the research, the investigator takes the following additional actions:

…(2) The investigator must obtain a translated copy of the IRB-approved English version of the long form that served as the written summary, which should be done promptly. The investigator promptly submits it to the IRB for review and approval. Once the translated long form/written summary is approved by the IRB, the investigator must provide it to the subject or LAR and should do so as soon as possible. FDA considers this step essential to the requirement that informed consent be documented by the use of a written consent document and that the subject be provided a copy (21 CFR 50.27). Many of the clinical investigations regulated by FDA involve ongoing interventions and may involve long-term follow-up. For this reason, translation of the long form is critically important as a means of providing subjects or their LAR an ongoing source of information understandable to them."

DHHS OHRP Guidance: Informed Consent of Subjects Who Do Not Speak English (1995)

"Where informed consent is documented in accordance with §46.117(b)(1), the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them. OHRP strongly encourages the use of this procedure whenever possible."

FAQs and Additional Guidance for Study Teams

1. **Does this requirement apply retroactively to participants that have been enrolled using a short form, or only for newly enrolled participants as of the policy effective date?**
   No. This requirement applies to participants consented and enrolled using the short form on or after the policy effective date of January 31, 2025.

2. **Does this requirement apply to all DF/HCC research studies, including minimal risk studies?**
   Yes. DF/HCC policy does not differentiate between study types for this requirement.

3. **Who is responsible for coordinating and paying for the translation of the long form consent document?**
   The coordination and cost of obtaining the translated consent document is the responsibility of the investigator at the site where the participant is being enrolled (note that the submission of the amendment for IRB approval is coordinated by the Core site, per question 4 below). Investigators should include the cost of written translations, as well as medical interpreter services, in their study budgets. Institutional support *may* be available; teams should work with their institutional clinical trials offices for additional guidance.
   For externally sponsored research - Industry sponsors are often willing to pay the cost of translating consent forms. We recommend teams work with industry sponsors to determine if translation costs are incorporate into

the budget.

4. **Who is responsible for coordinating IRB review and approval of the translated copy of the consent document?**
   The DF/HCC Core Site is responsible for coordinating submissions to the IRB, including ensuring that the translated consent document is submitted to, reviewed, and approved by the IRB of record.

5. **Once a consent form is translated, do we need to continue to keep it updated (e.g., with any amendment to the consent form) going forward?**
   Yes, best practice is to keep the translated consent form updated. The study team should consider the following: If the enrolled participant requires notification of new risk or reconsent, the fully translated, updated consent form should be available. Even if the participant initially enrolled speaking that language is off study, there is still a possibility of new risks that require notification or reconsent of off-study participants. Further, the regulations clearly state that once a short form is used, it should be considered "expected" that another participant speaking that language may be enrolled, and the short form should not be used when this is expected.

6. **Which study team member(s) may fulfill the requirement to provide the participant with a copy of the translated long form consent document?**
   CON-101 requires documentation in the appropriate research chart or medical record that the translated consent doucment was provided to the participant. Therefore, the translated consent document should be provided to the participant by a delegated study team member who is able to complete this documentation requirement.

7. **If while in the process of obtaining the translated long form consent document, another participant who speaks that language needs to be enrolled, how should the study team proceed? Do they need to wait for the full translated consent document to be used for the new potential participant?**
   The team should not unnecessarily delay the consent process with the new prospective participant while waiting for the approved, translated long form. In this case, it would be appropriate to obtain consent from the new participant using the short form method, and then ensure they are provided a copy of the translated long form once it is available.

8. **What should teams do if there is a delay in obtaining approval of an updated, translated consent document, impacting the timeliness of reconsenting a participant?**
   Consider including a plan for this in the notification/reconsent plan submitted to the IRB. For example, it may be appropriate to use verbal notification or use a short form with the updated English consent document to obtain reconsent. Keep in mind that if verbal notification is appropriate, you would still need to obtain reconsent once the translated consent document is approved and if you use the short form, you will still need to provide the fully translated consent document to the participant in a timely manner.

9. **Do other participant-facing documents also need to be translated following the use of the short form? (e.g., drug diaries, surveys, etc.)**
   DF/HCC policy specifically requires that the consent document be translated. It is generally best practice to obtain translated copies for other participant facing documents when possible. For documents that are provided

by an external sponsor, we recommend reaching out to the sponsor to determine whether they will be providing translated copies.

10. **Is there guidance for avoiding duplicating translation efforts between sites (e.g., if one site initiates translation for a language and before that document is approved, another participating site enrolls a participant using the short form who also speaks that language)?**
    Teams are expected to develop a communication plan to avoid duplication of efforts. Communication methods may vary between teams, but we would recommend that participating sites always check in with core site before they pursue translation to see if it may already be something another site is working on. This will help communication as the Core site will know to expect the documents for iRIS submission and will be aware the translation is in process at one site in case another site asks.

I still have questions. Who can I ask?

- Institutional cancer center clinical trials offices – Questions related to operationalizing this requirement and sites-specific guidance
  - BIDMC Cancer Clinical Trials Office (CCTO)
  - DFCI Clinical Trials Office (CTO)
  - MGH Cancer Center Protocol Office (CCPO)

- Office of Data Quality (ODQ) – Questions about DF/HCC policy requirements

- Office for Human Research Studies (OHRS) – Questions about submissions to the IRB, review and approval, short form and other consent templates, or other IRB-specific guidance