



## Monday Morning Practice Pearls #24

**You learn that your patient doesn't speak English and you don't have an IRB-approved protocol consent in the patient's native language. What do you do?**

### **Part 1: Ensuring IRB Approval, Obtaining Short Form & Securing Interpreter**

This type of enrollment is referred to as an “unexpected” enrollment and a short-form consent process may be used. According to the regulations ([OHRP](#) and [FDA](#)), [NIH HRPP SOP](#), [CC MAS Policy](#), and [CCR SOP](#), you will need to use the short-form consent process for this patient. Before you begin the face-to-face consent process you will need to:

1. Ensure that a short form consent document is available in the patient's native language. If not, one will be needed before you can proceed. Contact the NIH IRB Office (IRBO): [IRB@od.nih.gov](mailto:IRB@od.nih.gov) or 301-402-3713.
2. Ensure the protocol application includes prospective approval of short-form process
3. Obtain the appropriate version of the short form consent document
4. Secure an interpreter

Below is a summary of the activities involved.

<b>Ensuring IRB Approval</b>
Review the protocol application in iRIS to ensure the IRB had prospectively approved the use of the short form process. If not, contact your PSO Manager.
<b>Obtaining the Short Form Consent Document(s)</b>
<ul style="list-style-type: none"><li>• IRB approved short form consent documents are available in over 45 languages on the NIH IRBO website: <a href="https://irbo.nih.gov/confluence/display/IRBO/Short+Form+Consents">https://irbo.nih.gov/confluence/display/IRBO/Short+Form+Consents</a>.</li><li>• There are two versions of each short form; which version to use depends on when your protocol was initially approved: before or after the Revision to the Common Rule. If your study was initially approved <b>prior to or on 01/21/2019</b>, select from that listing for Pre-Common Rule. If your study was approved <b>after 01/21/2019</b>, select from the Common Rule versions listing.</li><li>• For reference purposes, there is an English version of the short form consent on the website. However, the English short form is used for reference only – no one should sign the English short form.</li></ul>
<b>Securing an Interpreter</b>
<p>Unless the person obtaining consent is fluent in the patient's language, an interpreter will be needed. It is preferable that someone who is independent of the subject (e.g., not a close family member, significant other, partner, etc.) be the interpreter.</p> <ul style="list-style-type: none"><li>• To schedule an in-person interpreter, please place an order in CRIS for Language Interpreter - Social Work Department no later than 24 hours prior to the date the service is required. Please contact the Language Interpreters Program at 301-496-2792 from 7:30 a.m. to 4:30 p.m. Monday through Friday. Note: if the language needed is not a common language (e.g., Mandarin), more than 24 hours may be needed to secure an interpreter.</li><li>• If possible, provide the interpreter with the consent documents (English long form and specific language short form) ahead of time for their review.</li></ul>