SUMMARY OF NIH GUIDELINE FOR CONSENTING NON-ENGLISH SPEAKERS

MINIMAL RISK RESEARCH

SUBJECT TYPE	LONG FORM USE	SHORT FORM USE
Anticipated non-English speaking subject	- Must translate long form in anticipated languages.	- Not permitted
Unanticipated non-English speaking subject		- Permitted to use short form if no translated consent form exists. - Short form use limited to 3 times per language, then must translate if needed a fourth time.

MORE THAN MINIMAL RISK RESEARCH

SUBJECT TYPE	LONG FORM USE	SHORT FORM USE
Anticipated non-English speaking subject	- Must translate long form in anticipated languages.	- Not permitted
Unanticipated non-English speaking subject	- Delay consent until long form translated UNLESS PI deems in best interest of subject to not wait.	- Permitted to use short form if PI deems in best interest of subject and no translated long form exists. - Long form must be promptly translated and, after IRB approval, be provided to subject.

HANDLING MODIFICATIONS TO THE CONSENT FORM

	LONG FORM USE	SHORT FORM USE	If PI determines in best interest to consent/ re-consent prior to a translated long form being available
NEW non-English speaking subject	- Wait to consent subject until translated long form with the changes is available UNLESS PI deems in best interest of subject to not wait – see 3rd column of this table for additional guidance.	- Cannot use short form process.	- Can use outdated version of translated consent plus interpreter to explain the protocol including any pending changes to the consent and obtain consent. - Initially obtain signature on outdated version and later, also obtain signature on updated version of translated consent when it's available. - Document in the research and/or medical record that pending changes to the consent were verbally explained to the participant by an interpreter and the subject agreed to participate.

			NOTE: WCG and Advarra IRBs accept use of the above approach. However, if an NIH team is using an **External Reviewing IRB** and that IRB's policies directly conflict with the above approach, study teams should: 1) Wait to consent until the translated long form with changes is available. ***OR*** 2) If permitted by the Reviewing IRB, use the short form process with the English long form consent and submit an RNI to the NIH IRB office. The outdated translated long form must also be given to subjects at the same time. The long form must be translated and, following IRB approval, promptly provided to the subject for them to sign.
EXISTING non-English speaking subject needs re-consent	- Wait to re-consent subject until translated long form with the changes is available UNLESS PI deems in best interest of subject to not wait – see 3rd column of this table for additional guidance.	- Cannot use short form process.	- If it is necessary to inform the subject of the new information prior to the translated version being available, the subject should be informed verbally using an interpreter and this should be documented in the medical and/or research record. - Promptly obtain written consent with a signature when a new translated version of the long form is available. ***NOTE:*** WCG and Advarra IRBs accept use of the above approach. However, if an NIH team is using an **External Reviewing IRB** and that IRB's policies directly conflict with the above approach, study teams should: 1) Wait to consent until the translated long form with changes is available. ***OR*** 2) If permitted by the Reviewing IRB, use the short form process with the English long form consent and submit an RNI to

			the NIH IRB office. The outdated translated long form should also be given to subjects. When the long form with changes is translated and has IRB approval, it should be provided to the subject for them to sign.

ADDITIONAL GUIDANCE FOR TEAMS RELYING ON AN EXTERNAL IRB: If there is a conflict between an External IRB's policies and NIH's – take the most conservative approach to ensure compliance with both sets of requirements. In this case, it may mean that NIH teams must wait until the translated consent is available before consenting/re-consenting a participant.