











# DECISION AID

## Accommodating participants with communication barriers

e.g. Limited English proficiency, low literacy, visual and/or hearing impairments

Answer with respect to the main study only, not optional sub-studies.

SEQ	Issue and Guidance	Feasibility
1	Does the study offer the prospect of direct benefit to participants that is not available outside the research context? <i>This does not in and of itself determine whether study teams must or should make accommodations to overcome communications barriers. However, study teams are expected to make greater effort to be inclusive when there is a prospect for direct benefit.</i>	Yes 
		No 
2	Does the study require participants' continuing active engagement over time? <i>e.g. repeated in-person study visits, email, phone, or app follow-up. Note: In cases when immediate feedback is important to participant safety (especially during an intervention e.g. exercise, shifting stimuli), even real-time interpretation may not be practicable.</i>	No 
		Yes 
3	Are all or most study visits in conjunction with clinical care where medical interpretation is available, and/or is this a clinical trial ( <a href="#">NIH 2014 definition</a> )? <i>Medical interpreters are usually free of charge to both patients and providers.</i>	Yes 
		No 
4	Does the scientific aim or plan restrict study procedures and/or data collection to pre-specified language(s) or format(s)? <i>e.g. some tests of cognition are language-dependent; responses to visual v. auditory cues may require different studies.</i>	No 
		Yes 
5	Does the study rely on validated data collection instruments available only in pre-specified language(s) or format(s)? <i>This does not include novel instruments developed for the study. It does include mobile health apps licensed for the study.</i>	No 
		Yes 

If the weight of the answers tends toward **increased feasibility and/or import** overall, the study team

- *should plan to* enroll participants who have barriers to communication when the occasion arises, and
- *should analyze* the demographics of the expected study population, to anticipate a need for translation if the population includes a significant proportion of foreign language speakers.

If the weight of the answers tends toward **decreased feasibility and/or import**, it is probably acceptable to exclude participants who would require interpretation/translation of study visits and materials.

Study teams are encouraged to seek assistance from their departments to pay for written translations, and/or interpretation in non-clinical contexts, if this is not covered by sponsor.