

Standard Operating Policy and Procedure
OTO 101 - Informed Consent, version # 3
Attachment A – Assessing Comprehension of Informed Consent

Investigational Title: _____

Principal Investigator: _____

The following questions could be used to assess the subject's (or subject's LAR) comprehension of the informed consent form and discussion.

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?