This guidance document is used to determine whether non-exempt <Human Research> using a short form of consent documentation can be approved.

### 1. Criteria for approval of a short form of consent documentation

#### 1.1
- The short form is written in language understandable to the subject or LAR (see Footnote 1)

#### 1.2
- The short form states that the required elements of informed consent have been presented orally to the subject or LAR

#### 1.3
- The written summary embodies the required and appropriate additional elements in Section 4 of "REGULATORY GUIDANCE: Criteria for Approval (HRP-400)"

#### 1.4
- The summary is accurate and complete

#### 1.5
- For subjects who do not speak English, the witness is conversant in both English and the language of the subject.

#### 1.6
- The subject or LAR will sign and date the short form and the summary

#### 1.7
- The person obtaining consent will sign and date the short form and the summary

#### 1.8
- The witness will sign and date the short form and the summary

#### 1.9
- The subject or LAR will be given signed and dated copies of the short form and the summary

### 2. Additional considerations

#### 2.1
- Once a short form is used for a particular language, should the summary be translated into that language and future subjects have consent documented in writing using the long form?

#### 2.2
- Once a short form is used for a particular language, should the summary be translated into that language and provided to that subject?

### 3. Notes

### 4. Footnotes

#### 4.1
In general, the short form is a standard document translated into the subject or LAR’s language and the summary is an untranslated long form consent document.