

## **LEGEND REASONS FOR CHANGES**

The Western Institutional Review Board® (WIRB®) identifies changes it makes to consent forms by redlining (double-underlining) added wording and by striking out (lining through) wording that is to be removed. In addition, the following list (legend) of reasons for changes is provided. A superscript number (small number slightly above the printed line) that matches the list will appear where appropriate to help you understand the reason(s) for a change.

<b>Number</b>	<b>Reason</b>
01	Conform to federal regulations, ICH guidelines, or state or local laws
02	Accuracy (to agree with protocol)
03	Coercive/reassuring language
04	Board-required words, phrases, paragraphs or changes
05	Sponsor-required words, phrases, paragraphs or changes
06	Duplication of information
07	Improve subject protection/safety
08	Clarity/Correction/Consistency
09	Created new paragraph
10	Moved from another area of consent form
11	Form changed from first to second person except consent section in first person, as required by Board.
12	Required for investigator, institution, or country (investigator's location)
13	Submitted changes
14	Modifications previously approved by Board for this protocol