

NOTICE: CONSENT FORM CHANGES

Two copies of your consent form are enclosed. One copy shows the changes made by the Western Institutional Review Board[®] (WIRB[®]). Items shown with a line through them have been deleted. Items shown with a double underline have been added by WIRB[®].
THIS COPY IS FOR YOUR REFERENCE ONLY.

The second copy is your “clean” copy. The “clean” copy with the WIRB[®] stamp is the official approved version. **ONLY THE CONSENT FORM WITH THE APPROVAL STAMP MAY BE USED TO CONSENT YOUR SUBJECTS.**

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 on your redlined copy where appropriate to help you understand the reason(s) for a change.

Number	Reason
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