Complete this subform if a placebo will be used in place of standard therapy.

Choose one of the four choices below (delete the others):

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 | Standard therapy for this condition is not considered effective. |
|  | click here to describe supporting information or reference attachment |

**Or**

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 | Standard therapy for this condition is considered effective.**AND**The toxicity of standard therapy is such that patients routinely refuse treatment. |
| Insert description of the toxicity routinely experienced.The toxicity is click here to describe supporting information or reference attachment |

**Or**

|  |  |  |
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 | Standard therapy for this condition is considered effective.**AND**The toxicity of standard therapy is such that patients do not routinely refuse treatment.**AND**The use of placebo instead of standard treatment cannot cause irreversible health problems or extreme suffering. |
| Insert description of the risks of withholding standard therapy in the absence of unacceptable toxicity.click here to describe supporting information or reference attachment |

**Or**

|  |  |  |
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 | Standard therapy for this condition is considered effective.**AND**The toxicity of standard therapy is such that patients do not routinely refuse treatment.**AND**The use of placebo instead of standard treatment can cause irreversible health problems or extreme suffering. |
| Note: A strong justification for the use of placebo in this manner is required.click here to describe supporting information or reference attachment |