Human Research Protections (HRP) strives to ensure that people with disabilities have access to all services and content. If you experience any accessibility-related issues with this form or any aspect of the ZOT IRB application process, email [OR-Web-Support@uci.edu](mailto:OR-Web-Support@uci.edu) for assistance.

INSTRUCTIONS

This information is necessary for the IRB to determine whether the use of placebo, placebo-washout, or sham procedures are appropriate. For more information, visit [Placebo-Controlled Studies](https://research.uci.edu/human-research-protections/clinical-research/placebo-controlled-studies/).

Answer all questions succinctly using non-technical language as much as possible.

* If a question is a numbered list, respond with a corresponding numbered list.
* If a question is not applicable to the research, state “N/A”.
* If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary “back and forth” for clarification.

1. STUDY INFORMATION

**Short Title:** Specify the short study title.

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| Click or tap here to enter text. |

2. DISEASE/CONDITION

**Standard Treatment:**

1. Explain whether proven standard treatment/therapy exist to treat the disease/condition being studied and if it is considered effective.
2. Explain whether standard therapy is given to mitigate permanent harms (e.g., psychological harm, disfigurement or other serious adverse sequelae) or whether it is given to treat symptoms that constitute inconvenience or discomfort only.
3. Explain if the disease/condition being treated has the potential to progress to a higher risk condition if not actively treated (i.e., if assigned to placebo/washout).

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| Click or tap here to enter text. |

**Study Design:** Explain how the study design will minimize risks to participants.

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| Click or tap here to enter text. |

3. USE OF PLACEBO/SHAM PROCEDURE

**Placebo/Sham Rationale:**

1. Provide compelling and scientifically sound methodological reasons for use of placebo or sham procedure (e.g., the toxicity of the therapy is such that patients commonly refuse it).
2. Explain whether the natural fluctuation of the disease/condition is significant enough to necessitate the use of placebo or sham comparison to determine if the observed changes are due to treatment or natural history.
3. Explain whether it would be possible to predict the placebo or sham response rate in this study with a reasonable degree of accuracy.

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| Click or tap here to enter text. |

**Placebo/Sham Risks:** Clarify whether participants in the placebo group would be exposed to an increased risk of death, severe morbidity or disability, severe discomfort, or other long-term negative effects.

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| Click or tap here to enter text. |

4. USE OF PLACEBO WASHOUT

*This section is not applicable, end of form.*

**Washout Rationale:**

1. Provide compelling and scientifically sound methodological reasons for use of placebo washout.
2. Describe the risks specific to the placebo-washout phase of the study.
3. Describe the increased participant monitoring that will occur during the washout period and detail any rescue plans for participants whose disease/condition worsens.

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| Click or tap here to enter text. |

**Washout Period:** Specify the duration of the washout period.

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| Click or tap here to enter text. |