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| The purpose of this checklist is to provide support for individuals responsible for the scientific review of research. Use this checklist to determine whether the research has scientific validity. Scientific Reviewers and/or consultants conducting scientific review are to use this checklist and upload it into ETHOS. This form is required for studies requiring HRPP Facilitated Scientific Assessment. |
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| 1. Conflicting Interests

Do you have a conflicting interest that prohibits you from providing an unbiased evaluation (see HRP-001 Definitions)? [ ]  I DO NOT HAVE A CONFLICT OF INTEREST TO DECLARE.[ ]  I RECUSE MYSELF FROM REVIEW OF THIS PROJECT BASED ON A CONFLICT OF INTEREST. |
| 1. Background, Purpose, Research Questions and Aims and Hypotheses

Check if “Acceptable.” If box is not checked, please provide specific findings using the Stipulations box below. If you have comments that you would like to provide the PI, but do not require the PI’s response, please include them in the Comments box.  |
| [ ] [ ] [ ] [ ]  | Suitable background material, supported by an adequate literature review, provides the rationale for the proposed research and identifies gaps in knowledge or treatment that will be addressed.Stipulations: Comments: The purpose of the study is clearly stated.Stipulations: Comments: The importance of the study's contribution is clearly stated-that the study has the potential to provide new and useful knowledge.Stipulations: Comments: The research questions, specific aims and/or hypotheses are precisely stated and, if appropriate, are measurable/testable.Stipulations: Comments:  |
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| 1. Research Design and Methodology

Check if “Acceptable.” If box is not checked, please provide specific findings using the Stipulations box below. If you have comments that you would like to provide the PI, but do not require the PI’s response, please include them in the Comments box. |
| [ ] [ ] [ ] [ ] [ ] [ ]  | The study design and associated methodologies are clearly stated and appropriate for addressing the proposed research questions.Stipulations: Comments: A suitable study population is defined with appropriate rationale for inclusion/exclusion criteria.Stipulations: Comments: The sample size is adequate to achieve the objectives/end points of the protocol.Stipulations: Comments: A screening and recruitment strategy for successfully enrolling subjects is outlined. Stipulations: Comments:  The primary outcome measures (and secondary outcomes measures, as appropriate) are clearly defined and suitable for addressing the proposed research questions or hypotheses (data dictionary included, if necessary). Stipulations: Comments: If the study involves qualitative data, the data are defined and there is a clear strategy for the collection of the data (e.g. an interview guide). Stipulations:      Comments:       |
| [ ] [ ] [ ] [ ]  | The outcome measures are appropriate for addressing the proposed research questions or hypotheses.Stipulations: Comments:      A clear plan for statistical analysis is described, and the plan is appropriate for answering the proposed research questions or hypotheses.Stipulations: Comments :      The timeline for study procedures and data collection/analysis is clearly defined.Stipulations: Comments:      The principal investigator is qualified to conduct the research.Stipulations: Comments:       |
| [ ]  | One of the following is true: **(Check box that is true)**[ ]  Approved (i.e., No modifications are requested by this reviewer prior to submission to the IRB committee)[ ]  Not Approved (i.e., Stipulations noted above must be addressed in an amended protocol, along with responses to the reviewer's stipulations)Comments:       |