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| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following “HRP 311 Worksheet: Criteria for Approval and Additional Considerations” when reviewing the scientific review of an Investigator-Initiated research protocol that is greater than minimal risk. Consultants conducting scientific or scholarly review are to consult this checklist if needed. 1. For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the IRB reviewer(s) completes this checklist and the IRB Office retains this checklist in the meeting files.
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| 1. Overall Scientific and Scholarly Validity (If no is selected provide comments below)
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| [ ]  Yes [ ]  No | The protocol accurately describes the research in a clear, detailed protocol in terms of: |
| * Objectives
* Background
* Setting
* Procedures
 | * Data and safety monitoring plan
* Risks
* Potential benefits
* Alternatives to participation
 |
| [ ]  Yes [ ]  No | The research is likely to answer its proposed question. |
| [ ]  Yes [ ]  No | The protocol describes fairly the expected knowledge to be gained and its importance. |
| [ ]  Yes [ ]  No | The available background information (clinical and non-clinical) is adequate to support the proposed research. |
| [ ]  Yes [ ]  No | There is no other way to do this research that would reduce risks to subjects and still answer the scientific question. |
| [ ]  Yes [ ]  No | There are no other monitoring procedures needed that would reduce risks to subjects and not affect the science. |
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| 1. Resources for Clinical Trials (“N/A” if the research is not a clinical trial)
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| [ ]  Yes [ ]  No [ ]  N/A | The available nonclinical and clinical information on an investigational product, including the investigator’s brochure (if applicable), is adequate to support the proposed clinical trial.  |
| [ ]  Yes [ ]  No [ ]  N/A | The investigator has demonstrated (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period. |
| [ ]  Yes [ ]  No [ ]  N/A | The investigator has sufficient time to properly conduct and complete the trial within the agreed trial period. |
| [ ]  Yes [ ]  No [ ]  N/A | The investigator has available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely. |
| [ ]  Yes [ ]  No [ ]  N/A | The investigator will ensure that all persons assisting with the trial are adequately informed and will receive appropriate training about the protocol, the investigational product(s), and their trial-related duties and functions. |
| [ ]  Yes [ ]  No [ ]  N/A | A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, will be responsible for all trial-related medical (or dental) decisions. |
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| Comment on the above:       |