**INVESTIGATOR CHECKLIST FOR SUBMITTING new RESEARCH PRoposal for Institutional Review Board**

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| --- | --- | --- | --- | --- |
| **Title of research proposal**: | | | | |
|  | **Yes** | **No** | **NA** | **This can be found on page** |
| 1. In a brief statement of one or a few sentences, did you state clearly and concisely the question that is being asked? |  |  |  |  |
| 2. Did you state what the study’s major outcome is? If you are measuring many outcomes, did you state which one is the main one? |  |  |  |  |
| 3. Did you describe the background underlying this research question, the previous literature that has addressed this issue, and the deficiencies in the previous studies that necessitate additional research in this area? |  |  |  |  |
| 4. Did you describe in detail the methods you will use to answer the main research question? |  |  |  |  |
| 5. Did you describe in detail the subsets of research questions? |  |  |  |  |
| 6. Did you describe the expected results of the research? |  |  |  |  |
| 7. Did you describe the statistical methods, which will be used to predict the likelihood that the results observed are due to actual differences rather than random occurrences? |  |  |  |  |
| 8. Did you define your sample size and how much power this gives you? |  |  |  |  |
| 9. Did you consult a statistician? |  |  |  |  |
| 10. Did you discuss the sources of bias (such as selection bias or recall bias) as well as confounders that may affect this study? |  |  |  |  |
| 11. Did you discuss how confounders (other risk factors that may be associated with the outcome) will be treated in this study? |  |  |  |  |
| 12. Did you include the number of study participants (local and all sites)? |  |  |  |  |
| 13. Did you provide the number of study sites? |  |  |  |  |
| 14. Did you state what the expected length of the subject’s participation is? |  |  |  |  |
| 15. Did you explain how will subjects be selected? Did you include inclusion and exclusion criteria? |  |  |  |  |
| 16. Did you include a data collection form? |  |  |  |  |
| 17. Did you state the source of funding and describe the budget for the study and justification for the items? |  |  |  |  |
| 18. Did you include study references page(s)? |  |  |  |  |
| 19. Did you include your work plan? |  |  |  |  |