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| The purpose of this worksheet is to provide support for individuals responsible for the scientific review of research. Use this worksheet to determine whether the research has scientific or scholarly validity. IRB members conducting scientific or scholarly review are to consult this worksheet for each protocol. This worksheet is to be used. It does not need to be completed or retained. Consultants providing scientific or scholarly review are to complete this worksheet and provide it to IRB staff who will retain it in the files. | | | | |
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| 1. Overall Scientific and Scholarly Validity | | | | |
| Yes  No | The research protocol is scientifically sound or has scholarly merit. | | | |
| 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 knowledge to be gained has importance. | | | |
| Yes  No | The available background information (clinical and non-clinical) is adequate to support the proposed research. | | | |
| Yes  No | Is there another way to do this research that would reduce risks to subjects and still answer the scientific question? | | | |
| Yes  No | Are there any monitoring procedures 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) | | | | |
| 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 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: | | | | |