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| The purpose of this worksheet is to provide support for individuals responsible for the scientific review of research during initial review and review of substantive amendments. Use this worksheet to determine whether the research has scientific or scholarly validity. Department and affiliate reviewers conducting scientific or scholarly review are to complete this worksheet and upload it into MGS IRB when they complete their review. | | | |
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| 1. Overall Scientific and Scholarly Validity (Check if “Yes”. All must be checked.) | | | |
|  | The protocol and associated documents accurately describe the research in a clear, detailed manner in terms of: | | |
| * Objectives * Background * Setting * Procedures | * Data and safety monitoring plan * Risks * Potential benefits * Alternatives to participation | |
|  | There is no other way to do this research that would reduce risks to subjects and still answer the scientific question. | | |
|  | There are no other monitoring procedures needed that would reduce risks to subjects while not affecting the science. | | |
|  | The research is likely to answer its proposed question. | | |
|  | The protocol adequately portrays the knowledge expected to result. | | |
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| 1. Clinical Trials (Check if “Yes.” All must be checked if the research is a Clinical Trial.)  N/A - not a Clinical Trial | | | |
|  | The available nonclinical and clinical information for an investigational product is adequate to support the proposed clinical trial. | | |
|  | The Investigator has demonstrated (e.g. based on retrospective data) the potential for recruiting the required number of suitable subjects within the agreed recruitment period. | | |
|  | The Investigator has sufficient time to properly conduct and complete the trial within the agreed trial period. | | |
|  | 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. | | |
|  | 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. | | |
|  | 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: | | | |