



WORKSHEET: Scientific or Scholarly Review

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 use this worksheet but do not need to complete or retain it. Consultants providing scientific or scholarly review are to complete this worksheet and provide it to IRB staff who will retain it in the files.¹

1. Overall Scientific and Scholarly Validity (Check if “Yes”. All must be checked)

- 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
- 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 and not affect the science.
- The research is likely to answer its proposed question.
- The protocol fairly portrays the knowledge expected to result.

2. Clinical Trials (Check if “Yes” or “NA”. All must be checked if the research is a Clinical Trial.)

- The available nonclinical and clinical information on an investigational product is adequate to support the Clinical Trial.
- 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.
- 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.

3. Comments

Comment on the above:

Click or tap here to enter text.

ⁱ This document satisfies AAHRPP elements I.1.F, I-9, II.2.E-II.2.E.2, II.3.A