

II1 GD1 Review of IRB Protocols by Consultants

Overview

In order to ensure that the rights and welfare of research participants are adequately protected, the Institutional Review Board (IRB) may request a consultant review a particular protocol and provide comments based on her or his expertise, knowledge and experience. To facilitate review, this guidance was prepared to bring attention to areas of interest to the IRB. The IRB may request comments from a consultant on one or more of the areas listed below.

II1A Risks and Benefits of the Research

Assess and comment on scientific soundness of the study design.

Comment on whether the research is likely to provide benefits, either to the participants themselves or through the knowledge that is likely to be gained.

Comment on whether the study design minimizes risks to participants and whether it is feasible and appropriate to find ways to further minimize risks.

II1B Proposed Participant Population

Describe whether the proposed participant population is appropriate for this research.

Identify any individuals in the proposed population who are at higher risk of harm from the research.

Explain why and whether they should be excluded.

Identify any additional protections that could be included in the study design to protect these participants.

Assess the overall study design with consideration for cultural practices among the population and field of study.

II1C Informed Consent

Explain whether the consent process is or is not appropriate for the proposed participant population.

Assess whether or not the consent process and documents are likely to be understood by the participants. If no, provide recommendations for improvement.

II1D Participant Safety

Assess the adequacy of the plans for monitoring the participants and the data for ensuring that emergent risks are identified in a timely manner.

II1E Privacy and Confidentiality

Comment on whether there risks to participants should the data be disclosed (accidentally or inappropriately accessed).

Assess the adequacy of the security to minimize unauthorized or inappropriate disclosure and any associated risks.

Describe cultural or other issues for this population that cause concern should the data be disclosed or seized.