100 GD.6 Review of Institutional Review Board (IRB) Protocols by Consultants

Overview

In order to ensure that the rights and welfare of research participants are adequately protected, the IRB may request that a consultant review a particular protocol and provide comments based on his/her expertise and/or experience. To facilitate review, the areas of interest to the IRB are outlined below. The IRB may request comments from a consultant on one or more of these areas.

Risks and Benefits of the Research

Comment on the study design. Is the design scientifically sound? Why or why not?

Comment on whether the research is likely to provide benefit, either to the participants themselves or to society 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.

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 or if there are additional protections that could be included in the study design to protect these participants.

Informed Consent

Explain whether the consent process is or is not appropriate for the proposed participant population. Is the consent process and document(s) likely to be understood by the participants? If not, please provide recommendations for improvement.

Participant Safety

Are the plans for monitoring the participants and the data adequate to ensure that emergent risks are identified in a timely manner?

Privacy and Confidentiality

Comment on whether there risks to participants should the data be disclosed (accidentally or inappropriately accessed) and if so are there adequate security measures in place to minimize these risks?

Are there cultural or other issues for this population that cause concern should the data be disclosed to unauthorized persons, or seized?

Is the overall study design in keeping with the practices of the culture and field of study?