MCLA IRB Protocol Outline

Research protocols must include the following information:

a) Abstract: This section should explain the specific nature of the study with clear justification for the participation of human subjects at this stage of the investigation. Researchers should keep in mind that most members of the IRB are not experts in the research being reviewed. Adequate explanations should be provided to allow the members of the IRB to understand the objectives, the methods, and the research implications, especially noting any procedure that may cause harm or injury (*risk*) in any way.

b) Participants: This section should note who the participants will be and how they are to be recruited. Justification must be provided for the use of subject groups that are members of a population whose capability for providing informed consent is absent or limited. These include children, persons with mental disabilities, and those who are confined to institutions (*whether voluntary or involuntary*). A detailed and specific discussion of potential problems involving the subject groups must be given.

c) Consent: A detailed description on how informed consent (*Informed consent means the knowing consent of an individual or his/her legally authorized representative so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.*) will be obtained. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

   If the proposed research includes minors (*under 18 years*) then the protocol needs to describe how both Parental/Guardian Informed Consent and Assent (a simpler version of the Consent Form, provided in age appropriate language for the minor) will be obtained. Copies of the Informed Consent and Assent forms need to be included in the proposal.

   If a waiver of Consent (or Informed Consent) is requested, the protocol must detail why Consent (or Informed Consent) is not necessary or not practical.

d) Risks: A discussion of the risks, even if they are anticipated to be minimal, is required. Risks may be physical, psychological or social. Some research involves neither risk nor discomfort, but rather violations of normal expectations. Such violations, if any, should be specified.

   Further, discussion of the management of risk is required. Procedures for protecting against or minimizing potential risks should be described. An assessment of their likely effectiveness should be discussed. Management of risk procedures ranges from those applicable to a group to those applicable to an individual subject.

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e) Benefits: This section must present a justification for the proposed study. The discussion should focus on the significance of the new knowledge that is being sought and an evaluation of the direct benefits to participant(s) (i.e. credit, awareness, gift) with respect to the risks involved in the study.

f) Confidentiality: Describe how confidentiality will be maintained within the proposed research, with consideration for:
- the separation of informed consent documents and results of such items as a completed surveys or data gathered
- the protection of participants' anonymity or a description of why select participants will not remain anonymous
- the protection of confidentiality in presentations or publications

g) Debriefing: A debriefing summarizes the research for the participant and provides contact information for any follow up questions or concerns. While a debriefing for a low-risk study may be short and delivered verbally. In higher risk research, a more in-depth statement in writing may be warranted. Regardless of how it is delivered to the research participant it should include:
- the purpose of the experiment
- the relation of the purpose to the conditions that they participated in
- the overall results and conclusions drawn from the experiment (*or where and when information about results will be available in the future*)
- Contact information of the researcher (when the Principal Researcher is a student, contact information for the faculty advisor)

A debriefing statement should be delivered in plain English (*i.e. not laden with jargon*) and provided to participants immediately after their participation.

h) Materials: Attach copies of all materials (*e.g., survey, etc.)* to be used in the study.

i) Other: Include any other information that may aid the IRB in the review process.