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Study Protocol Summary Documentation

Below is a **Study Protocol Summary Documentation** template that the researcher can provide to the Institutional Ethics Committee (IEC) of the East Delhi Physicians Association (EDPA) for submission. This structured template ensures that the researcher submits all essential details for a comprehensive ethical and scientific review by the IEC EDPA.

Study Protocol Summary

1. Title of the Study

Provide the full title of the research project in clear and concise language.

2. Principal Investigator (PI) and Team Information

- Principal Investigator:
 - Name:
 - Designation:
 - Institution/Organization:
 - Contact Information (Email/Phone):
- Co-Investigators and Team Members:
 - Names and designations of all co-investigators and collaborators involved.

3. Background and Rationale

Provide a brief overview of the scientific or clinical problem being addressed, including:

- Current state of knowledge and gaps in research.
- The relevance of the study in addressing the identified problem.

4. Objectives of the Study

Clearly define the primary and secondary objectives of the research.

5. Study Design

- Type of Study: Describe whether it is observational, interventional, randomized, etc.

- Methodology: Summarize the methods to be used, including population, interventions, and data collection.
- Endpoints: Define the primary and secondary endpoints/outcomes to be measured.

6. Study Population

- Target Population: Describe the group of participants the study aims to include.
- Inclusion Criteria: List the criteria for participant eligibility.
- Exclusion Criteria: List the criteria that would exclude individuals from the study.

7. Study Duration

Provide the estimated timeline for the study, including:

- Start and end dates.
- Duration of participant involvement.

8. Sample Size and Statistical Plan

- Sample Size: Specify the number of participants to be enrolled and justify the sample size calculation.
- Statistical Plan: Briefly describe the statistical methods to be used for data analysis.

9. Study Procedures

- Details of Interventions: Outline any drugs, devices, or procedures involved in the study.
- Participant Visits: Describe the number and frequency of visits, along with activities at each visit.

10. Ethical Considerations

- Informed Consent Process: Explain how participants will be informed and consented.
- Confidentiality: Describe measures to protect participant data and privacy.
- Risk-Benefit Assessment: Summarize potential risks and expected benefits.

11. Monitoring and Adverse Events Reporting

- Describe how the study will be monitored for safety.
- Outline procedures for reporting and managing adverse events.

12. Resources and Funding

- Funding Source: Provide details about the study's funding and sponsorship.
- Facilities and Equipment: Mention resources available to conduct the study.

13. References

List key references supporting the study.

14. Attachments

Include additional documents required for review, such as:

- Full Research Protocol
 - Participant Information Sheet (PIS)
 - Informed Consent Form (ICF) Template
 - Investigator's Curriculum Vitae (CV)
 - Budget and Financial Disclosure
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