**Guidelines for submission of Observational studies to Research review board, AIIMS, BATHINDA**

**Please Tick the relevant option**

1. **Overview of research Methodology**

 **Basic Sciences Clinical Cross Sectional Retrospective**

 **Epidemiological Public Health Case Control Prospective**

 **Socio behavioural Cohort Qualitative Systematic Review**

 **Quantitative Biological samples /Data Review Any others (Specify)**

**2. Nature of Study:**

**i. Faculty Driven Student Driven Specify details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**ii. Single Centre Multicentric (National) Multicentric (Global)**

**3. Duration of study:**

**4. Funding details and budget:**

**a. Type of study:**

**Non-funded Intramural/ Institutional Extramural**

**b. In case of funded study, fill the following details:**

**i. Specify type of funding agency:**

 **Government Private AIIMS, Bathinda**

**ii. Name of funding agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**iii. Estimated budget in INR:**

1. **Extramural fund (Sanctioned for AIIMS, Bathinda): \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Total (if multicentric): \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **Student/ Intramural fund (Funding sought): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**5. No of projects already submitted with IEC no:**

**6. No of projects completed with IEC no:**

 **7. Summary of proposed study in 1000 words including**

**a. STUDY TITLE**

**Indicate the study’s design with a commonly used term in the title without any abbreviations. (PICOT) if applicable**

1. **INVESTIGATORS (Justified, not the Guest/ Ghost investigators)**
2. **INTRODUCTION**

**Explain the scientific background and rationale for the investigation being reported**

**State Aims, Specific FINER Objectives (Only two), including any prespecified hypotheses**

1. **NOVELTY STATEMENT (Point wise)**
2. **METHODS**

**Study design**

**Settings**

**Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection**

**PARTICIPANTS RELATED INFORMATION**

**Type of participants in the study:**

**Healthy volunteer Patient Vulnerable person/ Special groups Others (Specify)**

**If vulnerable person /special group:**

**Children under 18 years Pregnant or lactating women Differently abled (Mental/Physical) Employees/Students/Nurses/ Staff Elderly Economically & socially disadvantaged Refugees/Migrants/Homeless Terminally Ill (stigmatized or rare diseases)**

 **Any other (Specify):**

**Is any of the clinician involved directly in clinical care of vulnerable population included as PI or CoI, if not justify**

 **Are there any incentives to the participant? Yes No**

**If yes; Provide details:**

**(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up. For matched studies, give matching criteria and number of exposed and unexposed**

**Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls For matched studies, give matching criteria and the number of controls per case**

**Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participant**

**INFORMED CONSENT:**

**1. Type of consent planned for:**

**i. Written Informed consent**

**ii. Audio-Video (A/V) consent**

**iii. Consent from LAR**

**iv. For children<7 yrs parental/LAR consent**

**v. Verbal assent from minor (7-12 yrs) along with parental consent**

**vi. Written Assent from Minor (13-18 yrs) along with parental consent**

**vii. Other (specify)**

**2. Participant Information Sheet (PIS) and Informed Consent Form (ICF):**

**English Hindi Others (specify)**

**VARIABLES**

**Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable**

**DATA SOURCES**

 **For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group**

**BIAS IF ANY**

**Describe any efforts to address potential sources of bias**

**STUDY SAMPLE SIZE**

**Explain how the study size was arrived at (WITH FORMULA EXPLANATION)**

**Sample size/ No. of Participants (as applicable)**

**a. At site: \_\_\_\_\_\_\_\_\_ India: \_\_\_\_\_\_\_\_\_\_\_ Globally: \_\_\_\_\_\_**

**b. Control group: \_\_\_\_\_\_\_\_\_\_\_\_ Study Group: \_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation**

**Is there an external laboratory/ outsourcing involved for investigations?**

**(If yes; provide details and attach relevant documents/MTA/ MoU etc.)**

**Statistical methods**

**(a) Describe all statistical methods, including those can be used to control for confounding**

**(b) Describe any methods which will be used to examine subgroups and interactions**

**(c) Explain how missing data will be addressed**

**(d) Cohort study—If applicable, explain how loss to follow-up will be addressed**

**Case-control study—If applicable, explain how matching of cases and controls will be addressed**

**Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy**

**(e) Describe any sensitivity analyses**

**6. EXPECTED OUTCOME**

**7. BENEFITS AND RISKS:**

**1. Are there any anticipated physical/social/psychological discomforts/ risk to participants?**

 **Yes No**

**2. If yes, categorize the level of risk:**

 **Less than Minimal risk Minimal risk**

 **Minor increase over minimal risk or Low Risk More than Minimal Risk or High Risk**

**3. What are the potential benefits from the study?**

 **Yes No If yes, Direct Indirect**

 **For the participant**

 **For the society/community**

 **For improvement in science**

**8. FUTURE IMPLICATIONS:**

**9. TIMELINE OF PROJECT WITH GANTT CHART**

**10. REVIEW OF LITERATURE**

**11. STORAGE AND CONFIDENTIALITY:**

**1. Who will be maintaining the data pertaining to the study? How long the data will be stored?**

**2. Whether provisions for maintaining confidentially and privacy of the participants have been addressed?**

**PUBLICATION, BENEFIT SHARING AND IPR ISSUES:**

**1. Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words)**

 **Yes No NA**

**2. Will the results of the study be reported and disseminated?**

 **Yes No NA**

**3. Is there is any commercial value or a plan to patent/IPR issues. If yes, Please provide details**

 **Yes No NA**

**12. DO YOU HAVE ANY ADDITIONAL INFORMATION TO ADD IN SUPPORT OF THE APPLICATION, WHICH IS NOT INCLUDED ELSEWHERE IN THE FORM? IF YES, PROVIDE THE DETAILS.**

 **Yes No**

**13. REFERENCES**