**Ethical Considerations Template for Ethics Review**

This template provides a framework for the ethical review of research proposals. It addresses key ethical principles and considerations to ensure the protection of participants and the integrity of the research process.

**2. Conflict of Interest (COI)**

2.1 Disclosure:

Does the PI or any member of the research team have any financial, familial, or proprietary interests that could potentially bias the design, conduct, or reporting of the study? (Yes/No]

If yes, please provide a detailed description of the COI and its potential impact: (Insert Description]

2.2 Management Plan:

Describe the plan for managing any identified COIs to minimize potential bias and ensure the objectivity of the research: (Insert Management Plan, e.g., independent data monitoring committee, blinding of researchers, etc.)

**3. Privacy and Confidentiality**

3.1 Data Collection Methods:

Describe the data collection methods to be used in the study: (Insert Description, e.g., surveys, interviews, medical record review, biological sample collection)

3.2 Privacy Protection:

What measures will be taken to protect the privacy of participants during data collection? (Insert Description, e.g., private interview rooms, anonymous surveys, etc.)

3.3 Data Storage and Security:

Describe the data storage and security procedures to ensure the confidentiality of participant information: (Insert Description, e.g., password-protected databases, encryption, limited access, secure physical storage, etc.)

3.4 Data Protection Plan:

Detail the data protection plan, including:

Who will have access to the data? (List individuals/roles)

How will data be de-identified or anonymized? (Describe the de-identification/anonymization process)

How long will the data be stored? (specify duration)

Where will the data be stored? (Specify location and security measures)

What procedures are in place for data sharing (if any)? (Describe data sharing agreements, if applicable)

**4. Informed Consent Process**

4.1 Respect for Persons:

Describe how the principle of respect for persons will be applied in the informed consent process: (Insert Description, e.g., providing sufficient information, ensuring comprehension, allowing voluntary participation, respecting the right to withdraw, etc.)

4.2 Consent Solicitation:

Who will solicit consent from potential participants? (List individuals/roles)

How will consent be obtained (e.g., in person, or online)? (Describe method)

When and where will consent be obtained (e.g., before any study procedures are initiated)? (Specify timing and location)

4.3 Consent Givers:

Who is authorized to give consent for participation in the study? (Specify, e.g., competent adults, parents/legal guardians for minors)

4.4 Special Populations:

Does the study involve any special populations who may require additional protections? (Yes/No)

If yes, describe the specific procedures for obtaining consent from these populations (e.g., assent from minors, consent from legally authorized representatives for individuals lacking capacity, community consultation for Indigenous populations): (Insert Description, include procedures for obtaining assent from children, if applicable and additional clearances necessary, ex. Indigenous People)

**5. Vulnerability**

5.1 Vulnerable Populations:

Does the study involve any vulnerable populations (e.g., children, the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable diseases, politically powerless people, or junior members of a hierarchical group)? (Yes/No]

If yes, identify the vulnerable populations and justify their inclusion in the study: (Insert Justification)

5.2 Informed Consent and Vulnerability:

Explain how the informed consent process will address the specific vulnerabilities of these populations to ensure their participation is truly voluntary and informed: (Insert Description of safeguards, e.g., providing additional explanation, involving advocates, ensuring comprehension, etc.)

**6. Recruitment**

6.1 Recruitment Methods:

Describe how participants will be recruited for the study: (Insert Description, e.g., advertisements, flyers, referrals, etc.)

6.2 Appropriateness:

Assess the appropriateness of the identified recruiting parties (e.g., healthcare providers, community leaders) and ensure that they are not in a position to unduly influence potential participants: (Justify the appropriateness of recruiting parties)

**7. Assent**

7.1 Feasibility of Assent:

If the study involves children, assess the feasibility of obtaining their assent to participate in the research, taking into account their age and maturity: (Assess feasibility)

7.2 Assent Procedures:

Describe the procedures for obtaining assent from children, including the use of age-appropriate language and explanations: (Insert Description]

7.3 Assent Age Brackets:

Indicate the age brackets for obtaining assent and the corresponding assent procedures:

0-Under 7 Years: No assent

7-Under 12 Years: Verbal Assent

12-Under 15 Years: Simplified Assent Form

15-Under 18 Years: Co-sign informed consent form with parents

**8. Risks**

8.1 Potential Risks:

Identify all potential risks to participants, including physical, psychological, social, and economic risks: (List Risks]

8.2 Risk Level:

Assess the level of risk associated with the study (e.g., minimal risk, more than minimal risk): (Assess Risk Level)

8.3 Risk Mitigation:

Describe the measures that will be taken to mitigate these risks and protect the safety and well-being of participants: $$Insert Description, e.g., safety protocols, counseling services, insurance coverage, etc.]

8.4 Adverse Event Management:

Detail the plan for managing adverse events, including procedures for reporting, documenting, and providing medical care to participants who experience adverse events: $$Insert Adverse Event Management Plan]

8.5 Justification for Placebo (If Applicable):

If a placebo is used in the study, provide a detailed justification for its use in accordance with the principles outlined in the Declaration of Helsinki: (Insert Justification)

**9. Benefits**

9.1 Direct Benefits:

Describe any potential direct benefits to participants who enroll in the study: $$Insert Description]

9.2 Generalizable Knowledge:

Assess the potential of the study to yield generalizable knowledge about the participant's condition or problem: (Assess Potential)

9.3 Non-Material Compensation:

Describe any non-material compensation to the participant (health education or other creative benefits): (Insert Description)

**10. Incentives or Compensation**

10.1 Justification for Incentives:

Justify offering any financial incentives or compensation to participants: (Insert Justification, e.g., reimbursement for time, travel expenses)

10.2 Amount and Method:

Describe the amount and method of compensation, financial incentives, or reimbursement of study-related expenses: (Insert Description]

10.3 Undue Influence:

Assess whether the amount or method of compensation could unduly influence potential participants to enroll in the study: (Assess Potential for Undue Influence)

**11. Community Considerations**

11.1 Community Impact:

Assess the potential impact of the research on the community where the research occurs and/or to whom findings can be linked, including issues like stigma or draining of local capacity: (Assess Impact)

11.2 Cultural Sensitivity:

Describe how the research will be conducted in a manner that is sensitive to the cultural traditions and values of the community: $$Insert Description]

11.3 Community Involvement:

Describe the plans for involving the community in decisions about the conduct of the study: $$Insert Description, e.g., community advisory boards, consultations, etc.]

**12. Collaborative Study Terms of Reference**

12.1 Multi-Institutional/Multi-Country Studies:

If the study is a multi-institutional or multi-country collaboration, provide a summary of the terms of reference, including:

Intellectual property rights: (Describe allocation of IP rights)

Publication rights: (Describe publication policies)

Information and responsibility sharing: (Describe information sharing procedures)

Transparency: (Describe procedures for ensuring transparency)

Capacity building: (Describe plans for capacity building at participating sites)

Reviewer Assessment:

**Overall Ethical Acceptability**: (Acceptable/Acceptable with Modifications/Not Acceptable)

Justification: (Provide a detailed justification for the assessment, including any required modifications or areas of concern.)

Note: This template is intended as a guide and may need to be adapted to fit the specific needs of the research study. It is essential to consult with experts in research ethics and relevant regulations to ensure that all ethical considerations are adequately addressed.