**BUERB INFORMED CONSENT TEMPLATE**

 **Informed Consent Form**

[Study Title]

[Researcher/Principal Investigator/ Name]

[Researcher/Principal Investigator Title]

[Department]

[Contact Information - Phone & Email]

**1. Study Involves Research**

You are being asked to participate in a research study.

**2. Purpose of the Study**

The purpose of this study is to [Clearly and concisely state the purpose of the study in lay terms. E.g., "to understand the experiences of student nurses during their clinical rotations" or "to test the effectiveness of a new teaching method on student learning outcomes."].

**3. Study-Related Treatments and Probability for Random Assignment**

[If applicable, include this section. If not applicable, state: "This study does not involve random assignment to different treatment groups."]

If you agree to participate, you will be randomly assigned to one of two groups: [Describe Group 1, e.g., "the new teaching method group"] or [Describe Group 2, e.g., "the standard teaching method group"]. Random assignment means that you will be assigned to a group by chance, like flipping a coin. You have a [State percentage, e.g., "50%"] chance of being assigned to each group.

[Describe each treatment group in detail, including procedures, medications, etc.].

**4. Study Procedures**

If you agree to be in this study, the following will happen:

[Describe each procedure in chronological order. Be specific and use lay terms. For example:]

You will be asked to complete a pre-study questionnaire.

You will participate in [number] sessions of [describe intervention, e.g., group counseling, a new exercise program].

[If applicable] During these sessions, the following invasive procedures will be performed: [describe the procedures in detail]. This includes [explain risks, pain, or discomfort associated with the procedures].

You will be asked to complete a post-study questionnaire.

[If applicable] A follow-up interview will be conducted [time frame].

**5. Responsibilities of the Participant**

If you choose to participate, you will be responsible for:

Attending all scheduled sessions.

Completing all questionnaires honestly and to the best of your ability.

Informing the research team of any discomfort or concerns you experience.

[Add any other specific responsibilities relevant to your study.]

**6. Expected Duration of Participation**

Your participation in this study is expected to last approximately [State time frame, e.g., "six weeks," "three months"]. This includes [Specify the breakdown of time commitment for various activities. E.g., "one hour per week for six weeks for the sessions, and approximately 30 minutes for completing the questionnaires"].

**7. Approximate Number of Participants**

We plan to enroll approximately [State the number] participants in this study.

**8. Experimental Aspects of the Study**

[State which aspects of the study are experimental. For example:]

The use of [Specific intervention or procedure] is considered experimental because [Explain why it is experimental. E.g., "it has not yet been widely tested in this population," or "it is a new approach to [problem]"].

**9. Foreseeable Risks**

Participating in this study may involve some risks. These risks include:

[List all foreseeable risks, including physical, psychological, social, and economic risks. Be specific. Examples:]

You may experience some mild discomfort or fatigue after the [Procedure].

You may feel some emotional distress when answering questions about [Sensitive topic].

There is a potential risk of breach of confidentiality, although we will take every precaution to protect your privacy.

[For studies involving pregnant women, embryos, fetuses, or nursing infants, include specific risks.]

[If applicable, include risks to spouse or partner.]

**10. Risks from Placebo (If Applicable)**

[If a placebo is used, include the following:] If you are assigned to the placebo group, you will receive a [Describe the placebo. E.g., "sugar pill," "inactive substance"] that has no active ingredients. The risks associated with receiving the placebo are [List risks, e.g., "that your condition may not improve," or "you may experience side effects that are not related to the active treatment."].

**11. Reasonably Expected Benefits**

[Choose one of the following options and tailor it to your study:]

Option 1 (Direct Benefit): You may benefit from participating in this study by [Describe the potential direct benefits to the participant. E.g., "experiencing an improvement in your [Condition]," or "learning new skills that will help you manage [Problem]"]. However, we cannot guarantee that you will experience any direct benefit.

Option 2 (No Direct Benefit): You will probably not benefit directly from taking part in this study. However, the information we learn from this study may help others in the future.

**12. Expected Benefits to the Community or Society**

The results of this study are expected to [Describe the potential benefits to the community or society. E.g., "improve our understanding of [Problem]," or "help us develop more effective interventions for [Problem]"]. This knowledge may lead to [Describe the potential impact, e.g., "better treatments for [Condition]," or "improved educational practices"].

**13. Post-Study Access**

[If applicable, describe post-study access to beneficial interventions. If not applicable, state: "There is no plan to provide access to the study product or intervention after the study ends."]

After the study, if [mention product/intervention] has been proven safe and effective, you will have access to it through [describe how they will gain access].

**14. Alternative Procedures or Treatments**

[Describe alternative procedures or treatments that are available to the participant. If no alternatives exist, state: "There are no other known alternative procedures or treatments available for [Condition] at this time, however, you may seek other procedures or treatment that may be deemed necessary."]

**15. Compensation for Study-Related Injury**

If you are injured as a direct result of participating in this study, Bicol University will provide [Describe the compensation, insurance, or treatment entitlements. Be specific. Consult with BU's legal and risk management departments to determine appropriate language.]

Examples:

Medical Treatment

Compensation for Medical Expenses

**16. Anticipated Payment to Participants**

[Choose one of the following options:]

Option 1 (Payment): You will receive [Amount] for your participation in this study. This payment is intended to compensate you for your time and inconvenience. You will receive [Describe payment schedule].

Option 2 (No Payment): You will not receive any payment for participating in this study.

**17. Compensation for Disability or Death**

[State whether there is compensation for disability or death resulting from study-related injuries. This should align with BU's policies and legal requirements. Consult with your institution's legal and risk management departments to determine the appropriate language. If there are no plans of compensation, clearly state it.]

In the event of disability or death resulting from study-related injuries, [describe compensation or absence of compensation plan].

**18. Anticipated Expenses**

[State whether participants will incur any expenses as a result of participating in the study.]

You will not have any expenses for participating in this study.

**19. Voluntary Participation and Right to Withdraw**

Your participation in this study is completely voluntary. You have the right to refuse to participate, and you may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to withdraw, please inform the research team.

**20. Access to Medical Records**

Study monitors, auditors, the Bicol University Research Ethics Board (BUERB), and regulatory authorities will be granted direct access to your medical records for purposes ONLY of verifying clinical trial procedures and data. All these individuals are legally bound to maintain your confidentiality.

**21. Confidentiality**

Any information about you that is obtained from this study will be kept confidential to the extent permitted by law. Your name and other identifying information will not be used in any publications or presentations resulting from this study. The data will be stored securely and only authorized personnel will have access to it.

[Include limitations to the researcher’s ability to guarantee confidentiality, e.g., "While we will take every precaution to protect your privacy, we cannot guarantee absolute confidentiality. For example, there is a small risk that your identity could be discovered if [Describe potential risk, e.g., "your data is subpoenaed by a court of law," or "the data is hacked."]]."

**22. Use of Genetic Tests and Familial Genetic Information**

[If the study involves genetic testing, include the following. If not, state: "This study does not involve genetic testing or the use of familial genetic information."]

[Describe the policy regarding the use of genetic tests and familial genetic information. Include precautions to prevent disclosure of results to family members without consent. Examples:]

Genetic tests will be performed on your [Type of sample, e.g., "blood sample"] to [Describe the purpose of the tests].

The results of these tests will be kept confidential and will only be shared with you.

We will not disclose the results to your family members or others without your explicit consent.

[Describe procedures for secure storage and disposal of genetic information.]

**23. Use of Medical Records and Biological Specimens**

[Clearly state how medical records and biological specimens will be used.]

Your medical records and biological specimens taken during the study may be used for direct or secondary purposes. These include: [list what these will be used for, e.g., testing, training, quality assurance].

**24. Storage and Future Use of Biological Specimens**

[Describe plans to destroy, store, or use biological specimens.]

At the end of the study, the biological specimens will be [State whether the biological specimens will be destroyed or stored].

If specimens will be stored:

Duration: [Specify the storage duration]

Type of storage facility: [describe the facility]

Location: [specify the location]

Access information: [specify who has access]

Possible future use: [describe all the possible uses]

You have the right to refuse future use, refuse storage, or have the materials destroyed.

**25. Commercial Products from Biological Specimens**

[State whether commercial products will be developed and whether participants will benefit.]

There are no plans to develop any commercial products using your biological specimens. If, in the future, there would be commercial products, it is confirmed that you will not receive monetary or other benefit from such development

**26. New Information**

You will be informed promptly if new information becomes available that may be relevant to your willingness to continue participation in this study.

**27. Access to Study Results**

You will have access to the results of this study by [Describe how participants can access the results. E.g., "receiving a summary report," "attending a presentation," or "contacting the research team."]. The results will be available approximately [Time frame].

**28. Access to Records**

You have the right to access your records for this study, however, there may be limitations with what we are requesting from the BU Ethics Review Board. If approval for partial or non-disclosure of access is approved, it will affect your ability to access certain aspects of your records.

**29. Termination of Participation**

Your participation in the study may be terminated by the researcher/investigator or sponsor without your consent under the following circumstances:

[List the circumstances, e.g., "if you fail to comply with study procedures," "if your condition worsens," or "if the study is stopped early due to safety concerns."].

**30. Study Funding and Affiliations**

This study is sponsored by [Name of Sponsor] and is being conducted by researchers affiliated with Bicol University. The funds for this study are provided by [Nature and sources of funds].

**31. Researcher's Role**

[State whether the researcher is also the participant's healthcare provider. Choose one:]

The researcher, [Researcher's Name], is serving only as a researcher and is not your healthcare provider.

**32. Contact Information**

If you have any questions about this study, please contact:

[Researcher/Principal Investigator Name] at [Phone Number] or [Email Address].

In the event of a study-related injury, please contact:

[Contact Person Name] at [Phone Number] or [Email Address].

**33. Ethics Committee Approval**

This study has been reviewed and approved by the Bicol University Ethics Review Board (BUERB). If you have any questions or concerns about your rights as a research participant, including grievances and complaints, you may contact the BUERB at [Contact Information – burec@bicol-u.edu.ph].

**Statement of Consent**

I have read this consent form and have had the opportunity to ask questions. I understand the risks and benefits of participating in this study. I voluntarily consent to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Name (Printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legally Acceptable Representative Signature (If applicable)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness Name (Printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date