Shaheed Mohtarma Benazir Bhutto (SMBB) Institute of Trauma

Department of Research Development

Informed Consent

This is a generic sample form to help you address most situations. Please adapt as appropriate for your research protocol and institution.

Project Information	
Project Title:	Project Number:
ERC Ref No:	Sponsor:
Principal Investigator:	Organization:
Location:	Phone:
Other Investigators:	Organization:
Location	Phone:

Consent document must be clearly written and understandable to subjects. The language must be nontechnical (comparable to the language in a newspapers or general circulation magazine), and scientific, technical or medical terms must be plainly defined.

Informed Consent, whether oral or written, may not include language that appears to waive subjects' legal rights or appears to release the investigators or anyone else from liability for negligence.

1. PURPOSE OF THIS RESEARCH STUDY

- Include 3-5 sentences written in nontechnical language. Start your informed consent form with the following statement: "You are being asked to participate in a research study designed to..."

2. PROCEDURES

- Describe procedures: "You will be asked to do..."
- Identify any procedures that are experimental/investigational/non-therapeutic.
- Define expected duration of subject's participation.
- Indicate type and frequency of monitoring during and after the study.

3. POSSIBLE RISKS OR DISCOMFORT

Note that these include not only physical injury, but also possible psychological, social or economic harm, discomfort, or inconvenience.

- Describe known or possible risks. If unknown, state so.
- Indicate if there are special risks to women of child bearing age; if relevant, state that study may involve risks that are currently unforeseeable, e.g., to developing fetus
- If subject's participation will continue over time, state: "any new information developed during the study that may affect your willingness to continue participation will be communicated to you."
- If applicable, state that a particular treatment or procedure may involve risks that are currently unforeseeable (to the subject, embryo or fetus, for example.)

4. POSSIBLE BENEFITS

- Describe any benefits to the subject that may be reasonably expected. If the research is not of direct benefit to the participant, explain possible benefits to others.

5. FINANCIAL CONSIDERATIONS

- Explain any financial compensation involved or state: "There is no financial compensation for your participation in this research."
- Describe any additional costs to the subject that might result from participation in this study, e.g. expenditures expected in coming to the research venue etc..
- Please indicate any financial benefits to the subjects including therapeutic or diagnostic costs being covered by the study.

6. AVAILABLE TREATMENT ALTERNATIVES

- If the procedure involves an experimental treatment, indicate whether other non-experimental (conventional) treatments are available and compare the relative risks (if known) of each.

7. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

- Include statements like: "This study involves (minimal risk/greater than minimal risk)." In the event that greater than minimal risk is involved, provide the subject with the following information.
- "If you are injured as a direct result of taking part in this research study, emergency medical care will be provided by [name] medical staff or by transporting you to your personal doctor or medical centre". Indicate who will pay for this treatment.

8. CONFIDENTIALITY

- Describe the extent to which confidentiality of records identifying the subject will be maintained.

  "Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you."

  "However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor, or by SMBBIT ERC members".

  In addition, list steps to protect confidentiality such as codes for identifying data.

9. TERMINATION OF RESEARCH STUDY

Include a statement: "You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. You will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation. In the event you decide to discontinue your participation in the study,

- These are the potential consequences that may result: (list)
- Please notify (name, telephone no., etc.) of your decision or follow this procedure (describe), so that your participation can be orderly terminated.

In addition, your participation in the study may be terminated by the investigator or the sponsor without your consent."

10. AVAILABLE SOURCES OF INFORMATION

- Any further questions you have about this study will be answered by the Principal Investigator:

  Name:
  Phone Number:

- Any questions you may have about your rights as a research subject will be answered by:

  Name: _____
  Phone Number: _____

  If applicable:

- In case of a research-related emergency, call:

  Day Emergency Number: _____
  Night Emergency Number: _____

11. AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. **I understand that I will receive a copy of this form**.

Participant Name (Printed or Typed):_____

Date: _____

Participant Signature:_____

Date: _____

Principal Investigator Signature: _____

Date: _____

Signature of Person Obtaining Consent:_____

Date: _____

This application form has been adapted, with permission, from the SIUT CBEC.