The Diabetes Centre
A company set up under section 42 of the Companies Act, 2017

The Diabetes Centre	IRB/REB Research Application Form	Institutional Review Board (IRB)/ Research Ethics Board (REB)	Email: irb@tdc.com.pk Contact #: 051 111 111 832

IRB/REB Ref #_____

Submission Date:_____

Receiving Date:_____

Revision Date:_____

Basic Protocol Information

Project Title:

Principal Investigator
Name:
Title:
Department:
Email:
Phone:

If there are additional Investigators, please add below:

Study role:
Name:
Title:
Department:
Email:
Phone:

EXPECTED DATES OF RESEARCH
Start (date/month/year):
End (date/month/year):

HUMAN SUBJECTS RESEARCH TRAINING
GCP Training
Date completed:

Good Clinical Practice (GCP) training must be completed prior to requesting a review of your IRB protocol. NDAT CTN (Clinical Trials Network) GCP training certification is valid for 3 years. To complete the GCP training – go to https://gcp.nidatraining.org/

DISSEMINATION OF RESULTS
How are you intending to disseminate the results of the research? (Check all that apply)

☐ Journal article ☐Conference presentation ☐Academic white paper ☐Thesis / Dissertation
☐Other - specify:

FUNDING OF RESEARCH

Is your research part of an external grant or contract?

☐ Yes →Attach copy of the grant application or contract

☐No

SECTION 1

REVIEW CATEGORY AND JUSTIFICATION

1a. Please read carefully the following categories and indicate which *category or categories* best describe your research by checking the appropriate box.

☐ **Category 1 -** Full Review

☐ **Category 2 –** Expedited Review

☐ **Category 3 –** Exempt Review

1b. If Category 2 or Category 3 is selected, kindly provide justification:

SECTION 2

RESEARCH QUESTION AND DESIGN

2a. RESEARCH QUESTION

In simple terms, state the research question to be answered by this project.

2b. RESEARCH DESIGN

Provide a brief summary of the research design.

SECTION 3

RESEARCH PROCEDURES

3. Describe in <u>detail</u> the research procedure below the following inclusion criteria.

Please include:

- Approximate dates and duration of research
- Approximate number of participants
- Total number of observations, surveys, interviews, visits, etc.
- Time commitment required per participant (ex. 10 minute interview x 3 interviews per participant)
- Location of research / data collection
- Explain participant withdrawal procedures (i.e. how a participant will allowed to stop out of the study)

Research Procedure:

SECTION 4

PARTICIPANTS

4a. TARGET POPULATION

Describe the participant group to be studied below the following inclusion criteria.

Include:

- Description of the group to be studied and why
- Description of the inclusion / exclusion criteria for participants.
  - Include the rationale for the involvement of any special groups including children, prisoners, pregnant women, or subjects with cognitive impairments.
  - Describe the characteristics of the targeted participants, including gender, age ranges, ethnic background, and health/treatment status.
  - If women or minorities are excluded, provide justification.
  - Give the number of participants you anticipate including from each targeted group listed above.

Participant Group:

4b. RECRUITMENT PROCEDURES

Describe how you will recruit participants for the study below the following inclusion criteria.

Include:

- Describe participants will be recruited
- Describe how participants will be informed that their participation is voluntary
- Describe how participants can withdraw from the study

Recruitment:

4b.1 Will email, flyers, brochures, posters, letters, etc. be used to recruit participants?

☐No

☐ Yes → Attach the advertisement material, brochures, posters, letters, etc. with this application

4b.2 Will you give the participants any type of compensation (i.e. money, gifts, transport etc.) for participation.

☐No

☐ Yes → describe compensation

4c. RESEARCH SITE

Describe all sites where this research will take place.

SECTION 5
INFORMED CONSENT / ASSENT

5a. INFORMED CONSENT PROCEDURE

Describe how (oral or written) and when voluntary consent will be obtained from participants below the following inclusion criteria.

Include:

- Who will be responsible for obtaining consent from participants
- Who will be providing consent? (ex. The participant, a parent, guardian, etc.)

NOTE: If individually identifiable information such as images (video or photos), audio recordings, names or notable descriptions of participants will be published, shared or otherwise disseminated, the consent form must make this explicit to the participant.

Informed Consent Procedure:

5b. INFORMED CONSENT DOCUMENTS

Please attach copy of the ICF with translation in the applicable language

The consent form must include:

- Title of study (Title should match the title listed on this form – if not, explain why)
- The purpose of the research
- A description of the research procedure
- Aspects of the trial that are not standard care for your condition or are experimental
- Who can participate
- Location where the research will take place
- Length of time the participant is expected to participate
- A description of any potential risks to the subject, including physical, psychological, social harm, discomfort, or inconvenience
- Benefits of the research to society and/or to the individual
- How confidentiality of records identifying the participant will be maintained (including where the data is stored, who has access to the data and how long the data will be kept)
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
- A statement that the subject may withdraw from the study at any time without penalty
- Who to contact for answers to questions about the study, their rights as research subjects or in the event of a research-related injury or emergency

5c. Are the participants below 18 years of age?

☐No →Skip to Section 6.

☐ Yes → Assent is required. Complete 5d. and 5e.

5d. INFORMED ASSENT PROCEDURE

Describe how (oral or written) and when voluntary assent will be obtained from participants who are below the age of 18

SECTION 6

POTENTIAL RISKS AND BENEFITS

6a. Describe any potential <u>risks</u> to participants (physical, psychological, social, legal, etc.) below the following inclusion criteria.

Include:

- Description of risk
- Likelihood of risk
- Level of seriousness of risk
- Efforts / safeguards to minimize risk
- Justification for why risk is necessary for the research design
- Provision of medical or psychological resources for participants exposed to risks
- Indemnity insurance

Potential Risks:

6b. Describe how the results of this study will benefit society and/or the individual participant.

6c What, if any, <u>benefits</u> will the participants receive from participating?

SECTION 7
CONFIDENTIALITY AND DATA SECURITY

7a. Outline the specific steps that will be taken (i.e. during study participation, after study participation and with the publication of study results) to ensure the subject's participation will be confidential.

7b. Describe how and where the data will be kept so that the data remain confidential and secure.

7c. List who will have access to the data.

Attachments Included Check List (as appropriate):

- ☐ CVs of PI and research team
- ☐ Data collection instruments (surveys, focus group guides, tests, observation guides, etc.)
- ☐ Research external funding proposal
- ☐Informed consent form (with translated copies in regional language)
- ☐ Patient information sheet (with translated copies in regional language)
- ☐ Recruitment flyers ads, letters, emails, etc.
- ☐Approval letters from NBC
- ☐GCP Certification