PATIENT INFORMATION AND CONSENT FORM
(RESEARCH PROJECT)

(English Version)

1. **ATTACHMENT B**
   <RESEARCH TITLE>
2. **ATTACHMENT S (Patient Information and Consent Form)**
3. **ATTACHMENT G (Patient Information and Consent Form – *Genetic Sample*)**
4. **ATTACHMENT P (Subject's Material Publication Consent Form)**

CONTOH **ATTACHMENT B**

RESEARCH INFORMATION

Research Title: _____

Researcher's Name: _____

PMDC Registration No. : _____

INTRODUCTION

You are invited to take part voluntarily in a research study of drugs: insulin AB and human insulin DC. AB is a mixture of 25% insulin and 75% NPL. Insulin, fast-acting human insulin analog and NPL is longer acting insulin similar to NPH. Human insulin DC, a mixture of 30% regular human insulin and 70% NPH. Before agreeing to participate in this research study, it is important that you read and understand this form. If you participate, you will receive a copy of this form to keep for your records.

Your participation in this study is expected to last up to 10 weeks. Up to 120 patients will be participating in this study.

PURPOSE OF THE STUDY

The purpose of this study are to determine if, during the 1-month period, treatment with insulin AB twice a day when compared to treatment with human insulin DC twice a day in patients with type 2 diabetes will results in –

- better control of blood sugar levels
- fewer incidents of low blood sugar

It is possible that information collected during this study will be analyzed by the sponsor in the future to evaluate insulin AB and human insulin DC for other possible uses or other medical or scientific purposes other than those currently proposed.

QUALIFICATION TO PARTICIPATE

The doctor in charge of this study or a member of the study staff has discussed with you the requirements for participation in this study. It is important that you are completely truthful with the doctor and staff about you health history. You should not participate in this study if you do not meet all qualifications.

Some of the requirements to be in this study are:

- You must have had Type 2 Diabetes for at least 6 months.
- You must be at least 30 years old.
- You must follow your prescribed diet and insulin therapy, as determined by the study doctor, and willing to:
    - ✓ Follow Ramadhan fasting,
    - ✓ Check your own blood sugar levels,

You **cannot** participate in this study if:

- You are being treated for cancer, other than basal cell or squamous cell skin cancer.
- You have serious heart, liver, or kidney problems, or have had a kidney transplant.

STUDY PROCEDURES

At your first visit, if you agree to participate in this study, you will have a physical examination that may include a blood test. In addition, you will be asked to provide information about your medical history, including when your diabetes was diagnosed, your past and present diabetes therapies, any other medical conditions that you have, and any other medicines that you are taking. You will be given instructions about an appropriate diet, how to use the insulin injection device, how to check your own blood sugar, the signs and symptoms of low blood sugar, and what to do if it occurs.

You will be asked to check your blood sugar :

1) before breakfast and
2) before dinner

These measurements should be recorded in a patient diary that you will be given and which you should bring to your next visit. If you continue in the study, you will be asked to do this again on 3 different days in the 5 days prior to visits 3 and 4.

At Visit 1 you will be given human insulin DC to use twice daily, once before breakfast and once before dinner, until your next visit (Visit 2). The study doctor will make adjustments to your insulin dose during this time period to help you get the best possible control of your blood sugar. If you are using metformin along with your insulin therapy at the time that this study begins, you will be allowed to continue using it, but you must remain on the same dose of metformin throughout the study.

Two to 6 weeks after your first visit, you will return for your second visit (Visit 2). AT this visit, if you qualify to continue in the study, you will be divided into one of two treatment groups. One group will continue to use human insulin DC twice a day, once before breakfast and once before dinner, for 2 more weeks.

RISKS

There may be risks to you if you participate in this study. Insulin AB has been taken by about 1,000 people in research.

A common bad experience reported by those taking any insulin, including insulin AB and human insulin DC, is low blood sugar. Some symptoms of having low blood sugar include lack of energy, hunger, confusion, pounding heart, sweating, tremor, and headache. Severe cases of low blood sugar may lead to unconsciousness and, in extreme cases, death.

For most people, needle puncture for blood draws do not cause any serious problems. However, they may cause bleeding, bruising, discomfort, infections and/or pain at the needle site or dizziness.

In addition to the risk named above, insulin AB and human insulin DC or the study procedures may have other unknown risks. You should follow carefully the doctor's directions for taking this study drug. You should not give the study drug to other people and should keep it out of the reach of small children. If any important new information is found during this study that may affect you wanting to continue to be part of this study, you will be told about it right away.

REPORTING HEALTH EXPERIENCES.

If you have any injury, bad effect, or any other unusual health experience during this study, make sure that you immediately tell the nurse or Dr. <researcher name> **[PMDC Registration No._____]** at <phone No.> or <H/P No.>. You can call at anytime, day or night, to report such health experiences.

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop participation in the study at anytime, without a penalty or loss of benefits to which you are otherwise entitled. Your participation also may be stopped by the study doctor or sponsor without your consent.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

Study drug and study procedures will be provided at no cost to you. You may receive information about your health from any physical examination and laboratory tests to be done in this study. We hope that the outcome and information regarding this research will beneficial to future patients.

QUESTIONS

If you have any question about this study or your rights, please contact;

<Name of Researcher> & <No. PMDC>
<Department of>
<School>
<IOD, CMH Lahore>
<Contact No. Office > <Contact No. HP>

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Prof. Dr. Muhammad Ashraf Chaudhry
MBBS, DPH, MPH(USA)
MSc, FCPS
Chairman
Ethical Review Board
Tel. No. : 042-36605550
Email : info@cmhlahore.edu.pk

CONFIDENTIALITY

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original medical records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying clinical trial procedures and/or data. Your medical information may be held and processed on a computer.

By signing this consent form, you authorize the record review, information storage and data transfer described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and data the signature page **[ATTACHMENT S or ATTACHMENT G (for genetic sample only) or ATTACHMENT P]**

Patient/Subject Information and Consent Form (Signature Page)

Research Title: _____

Researcher's Name: _____

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Patient Information and Consent Form to keep for myself.

_____ _____

Patient Name (Print or type) **Patient Initials** and **Number**

_____ _____

Patient N. I.C No. (New) **Patient N. I.C** No. (Old)

_____ _____

Signature of Patient or Legal Representative **Date** (dd/MM/yy)
(Add time if applicable)

_____

Name of Individual
Conducting Consent Discussion (Print or Type)

_____ _____

Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

_____ _____

Name & Signature of Witness **Date** (dd/MM/yy)

Note: i) All subject/patients who are involved in this study will not be covered by insurance.

Patient/ Subject Information and Consent Form (Signature Page)

Research Title: _____

Researcher's Name: _____

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
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- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Patient Information and Consent Form to keep for myself.

_____ _____

Patient Name (Print or type) **Patient Initials** and **Number**

_____ _____

Patient N.I.C No. **(New)** **Patient N.I.C** No. **(Old**)

_____ _____

Signature of patient or Legal Representative **Date** (dd/MM/yy)
(Add time if applicable)

_____

Name of Individual
conducting Consent Discussion (Print or Type)

_____ _____

Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

_____ _____

Name & Signature of Witness **Date** (dd/MM/yy)

Note: i) All subject/patients who are involved in this study will not be covered by insurance.
ii) Excess samples from this research will not be used for other reasons and will be destroyed with the consent from the Research Ethics Committee (Human), CMH.

Patient's Material Publication Consent Form
Signature Page

Research Title: _____

Researcher's Name: _____

To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there has been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist world wide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors world wide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.
- The materials will not be used out of contex – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

_____ _____

Patient Name (Print or type) **Patient Initials** or **Number**

_____ _____ _____

Patient N.I.C No. Patient's Signature **Date** (dd/MM/yy)

_____ _____

Name and Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

Note: i) All subject/patients who are involved in this study will not be covered by insurance.