Appendix A – Patient Consent Form (English version)

HKU Med LKS Faculty of Medicine
Department of Family Medicine & Primary Care
香港大學家庭醫學及基層醫療學系

CONFIDENTIAL

Research conducted by

Department of Family Medicine and Primary Care, HKU

Information and Consent Form

The development and validation of a DM and Pre-DM risk prediction function for case finding in primary care in Hong Kong

Principle Investigator: Prof. Cindy Lo Kuen Lam

Thank you for reading this information and agreeing to consider taking part in this study. Please read this form, and if **you have understood the purpose and procedure of the study and kindly agree to take part, please sign and date** at the end of this Consent Form.

Study information

This study aims to identify Chinese people at risk of pre-diabetes or diabetes by using a risk prediction model. Each participant will be invited to have a questionnaire interview and measurement of blood pressure, body height, body weight, waist and hip circumference to classify the risk of having pre-diabetes or diabetes. The questionnaire interview will be about 10-15 minutes. The participant will be invited to have a free blood test on oral glucose tolerance test, HbA1c, lipid profile and complete blood picture at an approved private laboratory to establish a diagnosis of pre-diabetes and diabetes. The test will be about 2.5 hours. This blood sample will be used for biochemical analyses for this study only. You may have pain during the blood test. If the first blood test result is normal, you will be invited to repeat the blood test 1 year after for follow-up process.

All the data collected from you will be kept confidential and no individual identity information will be disclosed in any reports, data record forms or publications. Please sign and date at the end of this Consent Form if you agree to take part in this study and understand the study information and process.

You can withdraw from the study anytime you want without infringement on any of your rights to treatment in this clinic or other services provided by the Hospital Authority.

For further information please contact:

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The University of Hong Kong
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Telephone: 2518 5653; Fax: 2814 7475

Declaration on Protection of Personal Data

Under the laws of the Hong Kong Special Administrative Region and, in particular, the Personal Data (Privacy) Ordinance, Cap 486, you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study.

By signing and dating this Consent Form, you agree to allow the collection, custody, retention, management, control, and use your personal data in this study in ways described in the Information Leaflet. For any query, you should consult the Privacy Commissioner for Privacy Data or his office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

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Consent Form

The following statements are to check that you understand and consent to the procedures involved in taking part in this research：

1. I confirm that I have read and understood (or had someone read and explained) the information for the above study and have been given a copy to keep. I have had the opportunity to ask questions about the project and I understand why the research is being done and any risks involved.
2. I understand that my participation is voluntary.
3. I agree to take part in the study.
4. I agree to allow the research team to obtain from my doctors and to extract from the Hospital Authority Medical Record System the relevant clinical data for the purpose of the study.
5. I agree to answer a questionnaire administered by the research assistant and have measurements on blood pressure, body height, body weight, waist and hip circumference, and to attend the blood tests on oral glucose tolerance test, HbA1c, lipid profile and complete blood picture if I am eligible for the study.
6. I understand that I may have pain during the blood test.
7. I understand that if the results are abnormal, the research team will inform me for the necessary follow up.
8. I understand that all information that I provide to the research team will be kept confidential and only the investigators and their research team will have access to it.
9. I understand how the data will be collected, that giving data for this research is voluntary and that I am free to withdraw the permission to use my data at any time, without giving reason and without my medical treatment or legal rights being affected.
10. I understand that I will not benefit financially from this research.
11. I understand that I am free to withdraw from the study at any time, without giving reason and without my medical treatment or legal rights being affected in any way.
12. I understand the investigators have the right to exclude me from the study in the event of inter-current illness, adverse event, protocol violations, or other reasons.

Please sign and date this Consent Form below:

_____	_____	_____
Name of Subject in BLOCK letters	Signature	Date
_____	_____	_____
Name of Investigator in BLOCK letters	Signature	Date

Dong W, *et al. BMJ Open* 2022; 12:e059430. doi: 10.1136/bmjopen-2021-059430