

## INFORMED CONSENT FORM

### 1. Study Information

**Protocol Title:**

The Impact of Collaborative Care Model in the Management of Primary Care Patients with Type 2 Diabetes Mellitus in Singapore

**Principal Investigator & Contact Details:****Overall Principal Investigator**

Ms. Tan Wei Yan Cheryl  
National Healthcare Group Pharmacy  
3 Fusionopolis Link, #05-07  
Nexus@one-north  
Singapore (138543)  
Tel: (65) 9821 0436 / (65) 6516 8014  
Email: cheryl\_wy\_tan@pharmacy.nhg.com.sg

**Site Principal Investigator**

Dr. Tsou Yu Kei Keith  
Director  
Clinical Services  
National University Polyclinics  
50 Bukit Batok West Avenue 3  
Singapore (659164)  
Tel: (65) 6496 6773  
Fax: (65) 6566 2208  
Email: keith\_tsou@nuhs.edu.sg

**Study Sponsor:**

Health Services Research Competitive Research Grant, Ministry of Health

### 2. Purpose of the Study

You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because you have type 2 diabetes mellitus which can be further improved, and are taking more than five chronic medications.

This study is carried out to find out the added values of collaborative care in helping you improve or achieve the control of your diabetes. Collaborative care involves active participation of clinical pharmacists in managing your diabetes on top of physician's visit.

This study will recruit 250 subjects from multiple institutions under National University Polyclinics (NUP). Each recruited subject will be followed up for a total of 1 year.

### 3. What procedures will be followed in this study

If you take part in this study, you will be randomized into two groups (refer to Table 1). Randomization means assigning you to one of the two groups by chance, like computerized assignment using opaque, sealed envelopes.

This study is twelve-month in length. If you take part in this study, you will be asked to answer a survey of about 45 minutes at the beginning of the study, at six months, and at twelve months (total time spent will be around 2 hours 30 minutes), administered by the Principal Investigator (PI) or her representative, at the beginning of the study, at six months, and at twelve months of the study. The survey consists of the following:

- Quality of life
- Diabetes distress
- Treatment satisfaction
- Self-care
- Productivity
- Hypoglycaemia

In addition, information about your laboratory tests and medications will also be extracted only for the purpose of this study and the representative may also call you for care- and administrative-related matters if needed.

If you are invited to see a healthcare team with a pharmacist for your diabetes care, you will also be asked to follow up with the team and follow their instructions. Some may require telephone-counselling, but most of the visits will be face-to-face. The healthcare team may provide:

- Counselling on medication therapy, self-care practices, exercise, and diet
- Modify medication dose and frequency
- Perform simple physical assessment, e.g. measure blood pressure, assess for swelling, etc.
- Order follow-up visits with the healthcare providers
- Order laboratory tests as appropriate

You will still be continuing with your regular visits to the doctor at least every 4-monthly.

If you agree to take part in this study, you will be randomized into one of the following groups:

**Table 1: Description of randomised groups**

	Group A: Usual care	Group B: Visit a healthcare team with involvement of a pharmacist
Care	Routine care with doctor as usual, and referral to nurse and/or dietitian as needed (number of visits are based on the need determined by your doctor)	Routine care with a healthcare team of doctors, nurses, and/or dietitians, (number of visits are based on the need determined by your healthcare team)  <u>AND</u> Visits with pharmacist at least every four to six weeks (face-to-face or via phone call).
Extracting information	Yes (from electronic medical records) <ul style="list-style-type: none"><li>• Laboratory tests, medical history, medication list, cost</li></ul>	Yes (from electronic medical records) <ul style="list-style-type: none"><li>• Laboratory tests, medical history, medication list, cost</li></ul>
Answering questionnaires	At the beginning At sixth month At twelfth month	At the beginning At sixth month At twelfth month

#### **4. Your Responsibilities in This Study**

If you agree to participate in this study, you should follow the advice given to you by the study team. You should be prepared to visit the hospital or polyclinics regularly as instructed by your healthcare providers (doctors, nurses, dietitians, and pharmacists as appropriate) and undergo all necessary procedures, including those outlined in Table 1.

#### **5. What Is Not Standard Care or is Experimental in This Study**

The study is being conducted because the collaborative care model is not yet proven to be a standard practice model in subjects with type 2 diabetes in Singapore. We hope that your participation will help us to determine whether a team-based care can add value to the current practice model.

Your health care providers will be informed about your participation in the study. However, they will not know which group you belong to. Only the study team knows which group you have been randomized to.

Although this care model may be part of standard medical care, in this study the involvement of pharmacists in the team is only being performed for the purposes of the research, and it is not part of your routine care. The administration and completion of the questionnaires are not part of your standard medical care and are conducted for research purposes only.

#### **6. Possible Risks and Side Effects**

There are minimal to no possible risks or side effects for participating in this study, except for a highly unlikely but potential risk of breach of confidentiality. As the collaborative care is to provide an added value, your standard of care or routine care is still being preserved. At any point in time, if you feel uncomfortable in answering the survey, you may stop and withdraw from the survey or session.

#### **7. Possible Benefits from Participating in the Study**

There is no assurance you will benefit from participation in this study. However, your participation in this study may add to the general knowledge to improve the care provided for the management of primary care patients with Type 2 Diabetes Mellitus in Singapore

#### **8. Alternatives to Participation**

If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be the usual care that you have been receiving before. This includes regular visits with doctors, nurses, and dietitians as appropriate.

#### **9. Costs & Payments if Participating in the Study**

If you take part in this study, you will be reimbursed for your time, inconvenience and transportation costs as follows:

- If you complete the first survey administered at the beginning of the study, you will be given a glucometer. The glucometer will not be replaced in the event of lost, stolen, or damaged. No more than four bottles (each with 50 glucose test strips and lancets) will be given to you as needed during the study. If you require additional strips and lancets, you will have to bear the costs for the extra strips and lancets. The glucose test strips and lancets will not be replaced in the event of lost, stolen, or damaged.
- If you complete six months of the study and a second survey, you will be reimbursed with S\$20 cash or equivalent at the sixth month.

- If you complete twelve months of the study and the last survey, you will be reimbursed with S\$30 cash or equivalent at the twelfth month.
- If you did not complete the study for any reason or withdraw from the study, you will not be reimbursed, and you will need to return the glucometer to the study team.

If additional ordering of laboratory tests and/or medications is deemed necessary during your visits with the healthcare team, you will have to bear the costs of the laboratory tests and medications. Participants randomized into the intervention group will not need to bear the additional cost of visiting the clinical pharmacist.

## **10. Voluntary Participation**

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should inform the PI.

If you withdraw from the study, you will be required to inform the PI and return the glucose meter to her or her representative. Refusal to participate or withdrawal from participation will not affect your medical management or cause loss of benefits to which you are otherwise entitled.

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your healthcare providers, the investigators and/or the sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the care team will decide if you may continue in the study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you will be informed in a timely manner by the PI or her representative.

## **11. Compensation for Injury**

If you follow the directions of the health care providers in charge of this study and you are physically injured due to the procedure given under the plan of this study, NHG Pharmacy and NUP will pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your treatment will not be provided by NHG Pharmacy and NUP.

NHG Pharmacy and NUP without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove NHG Pharmacy and/or NUP is/are at fault. There are however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your PI.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

## **12. Confidentiality of Study and Medical Records**

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

However, National University of Singapore, National Healthcare Group Pharmacy, National University Polyclinics, NHG Domain Specific Review Board, and Ministry of Health will be

granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you are authorizing (i) collection, access to, use, and storage of your “Personal Data”, and (ii) disclosure to authorised service providers and relevant third parties.

“Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. This includes medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this “Personal Data”, will be subject to review by the relevant institutional review board.

Data collected and entered into the Case Report Forms are the property of National University of Singapore, National Healthcare Group Pharmacy, and National University Polyclinics. In the event of any publication regarding this study, your identity will remain confidential.

*By participating in this study, you are confirming that you have read, understood and consent to the National University Health System Personal Data Protection Notification available at (<http://www.nuhs.edu.sg/personal-data-protection/nuhsnuh-data-protection-policy.html>) and National Healthcare Group Personal Data Protection Notification available at (<https://corp.nhg.com.sg/Pages/PDPA.aspx>).*

### **13. Who To Contact if You Have Questions**

If you have questions about this study, you may contact the PI.

#### **Overall Principal Investigator**

Ms. Tan Wei Yan Cheryl  
National Healthcare Group Pharmacy  
3 Fusionopolis Link, #05-07  
Nexus@one-north  
Singapore (138543)  
Tel: (65) 9821 0436 / (65) 6516 8014  
Email: cheryl\_wy\_tan@pharmacy.nhg.com.sg

#### **Site Principal Investigator**

Dr. Tsou Yu Kei Keith  
Director  
Clinical Services  
National University Polyclinics  
50 Bukit Batok West Avenue 3  
Singapore (659164)  
Tel: (65) 6496 6773  
Fax: (65) 6566 2208  
Email: keith\_tsou@nuhs.edu.sg

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at [www.research.nhg.com.sg](http://www.research.nhg.com.sg).

If you have any complaints or feedback about this study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

## CONSENT FORM

### Protocol Title:

The Impact of Collaborative Care Model in the Management of Primary Care Patients with Type 2 Diabetes Mellitus in Singapore

### Principal Investigator & Contact Details:

#### Overall Principal Investigator

Ms. Tan Wei Yan Cheryl  
National Healthcare Group Pharmacy  
3 Fusionopolis Link, #05-07  
Nexus@one-north  
Singapore (138543)  
Tel: (65) 9821 0436 / (65) 6516 8014  
Email: cheryl\_wy\_tan@pharmacy.nhg.com.sg

#### Site Principal Investigator

Dr. Tsou Yu Kei Keith  
Director  
Clinical Services  
National University Polyclinics  
50 Bukit Batok West Avenue 3  
Singapore (659164)  
Tel: (65) 6496 6773  
Fax: (65) 6566 2208  
Email: keith\_tsou@nuhs.edu.sg

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction. I have also been informed and understood the alternative treatments or procedures available and their possible benefits and risks.

*By participating in this study, I confirm that I have read, understood and consent to the National University Health System and National Healthcare Group Personal Data Protection Notification.*

\_\_\_\_\_  
Name of Participant                      Signature                      Date

### Translator Information

The study has been explained to the participant / legally acceptable representative in

\_\_\_\_\_ by \_\_\_\_\_  
(language)                      (name)





OFFICIAL USE ONLY	
Doc Name : Informed Consent Form Template	
Doc Number : 207-001	
Doc Version : 1	Date : 13 Mar 2018

## INFORMED CONSENT FORM

### 1. Study Information

#### Protocol Title:

The Impact of Collaborative Care Model in the Management of Primary Care Patients with Type 2 Diabetes Mellitus in Singapore

#### Principal Investigator & Contact Details:

##### Overall Principal Investigator

Ms. Tan Wei Yan Cheryl  
National Healthcare Group Pharmacy  
3 Fusionopolis Link, #05-07  
Nexus@one-north  
Singapore (138543)  
Tel: (65) 9821 0436 / (65) 6516 8014  
Email: cheryl\_wy\_tan@pharmacy.nhg.com.sg

##### Site Principal Investigator

Dr. Tsou Yu Kei Keith  
Director  
Clinical Services  
National University Polyclinics  
50 Bukit Batok West Avenue 3  
Singapore (659164)  
Tel: (65) 6496 6773  
Fax: (65) 6566 2208  
Email: keith\_tsou@nuhs.edu.sg

#### Study Sponsor:

Health Services Research Competitive Research Grant, Ministry of Health

### 2. Purpose of the Study

You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because you have type 2 diabetes mellitus which can be further improved, and are taking more than five chronic medications.

This study is carried out to find out the added values of collaborative care in helping you improve or achieve the control of your diabetes. Collaborative care involves active participation of clinical pharmacists in managing your diabetes on top of physician's visit.

This study will recruit 250 subjects from multiple institutions under National University Polyclinics (NUP). Each recruited subject will be followed up for a total of 1 year.

### 3. What procedures will be followed in this study

If you take part in this study, you will be randomized into two groups (refer to Table 1). Randomization means assigning you to one of the two groups by chance, like computerized assignment using opaque, sealed envelopes.

This study is twelve-month in length. If you take part in this study, you will be asked to answer a survey of about 45 minutes at the beginning of the study, at six months, and at twelve months (total time spent will be around 2 hours 30 minutes), administered by the Principal Investigator (PI) or her representative, at the beginning of the study, at six months, and at twelve months of the study. The survey consists of the following:

- Quality of life
- Diabetes distress
- Treatment satisfaction
- Self-care
- Productivity
- Hypoglycaemia

In addition, information about your laboratory tests and medications will also be extracted only for the purpose of this study and the representative may also call you for care- and administrative-related matters if needed.

If you are invited to see a healthcare team with a pharmacist for your diabetes care, you will also be asked to follow up with the team and follow their instructions. Some may require telephone-counselling, but most of the visits will be face-to-face. The healthcare team may provide:

- Counselling on medication therapy, self-care practices, exercise, and diet
- Modify medication dose and frequency
- Perform simple physical assessment, e.g. measure blood pressure, assess for swelling, etc.
- Order follow-up visits with the healthcare providers
- Order laboratory tests as appropriate

You will still be continuing with your regular visits to the doctor at least every 4-monthly.

If you agree to take part in this study, you will be randomized into one of the following groups:

**Table 1: Description of randomised groups**

	Group A: Usual care	Group B: Visit a healthcare team with involvement of a pharmacist
Care	Routine care with doctor as usual, and referral to nurse and/or dietitian as needed (number of visits are based on the need determined by your doctor)	Routine care with a healthcare team of doctors, nurses, and/or dietitians, (number of visits are based on the need determined by your healthcare team)  <u>AND</u> Visits with pharmacist at least every four to six weeks (face-to-face or via phone call).
Extracting information	Yes (from electronic medical records) <ul style="list-style-type: none"><li>• Laboratory tests, medical history, medication list, cost</li></ul>	Yes (from electronic medical records) <ul style="list-style-type: none"><li>• Laboratory tests, medical history, medication list, cost</li></ul>
Answering questionnaires	At the beginning At sixth month At twelfth month	At the beginning At sixth month At twelfth month

#### **4. Your Responsibilities in This Study**

If you agree to participate in this study, you should follow the advice given to you by the study team. You should be prepared to visit the hospital or polyclinics regularly as instructed by your healthcare providers (doctors, nurses, dietitians, and pharmacists as appropriate) and undergo all necessary procedures, including those outlined in Table 1.

#### **5. What Is Not Standard Care or is Experimental in This Study**

The study is being conducted because the collaborative care model is not yet proven to be a standard practice model in subjects with type 2 diabetes in Singapore. We hope that your participation will help us to determine whether a team-based care can add value to the current practice model.

Your health care providers will be informed about your participation in the study. However, they will not know which group you belong to. Only the study team knows which group you have been randomized to.

Although this care model may be part of standard medical care, in this study the involvement of pharmacists in the team is only being performed for the purposes of the research, and it is not part of your routine care. The administration and completion of the questionnaires are not part of your standard medical care and are conducted for research purposes only.

#### **6. Possible Risks and Side Effects**

There are minimal to no possible risks or side effects for participating in this study, except for a highly unlikely but potential risk of breach of confidentiality. As the collaborative care is to provide an added value, your standard of care or routine care is still being preserved. At any point in time, if you feel uncomfortable in answering the survey, you may stop and withdraw from the survey or session.

#### **7. Possible Benefits from Participating in the Study**

There is no assurance you will benefit from participation in this study. However, your participation in this study may add to the general knowledge to improve the care provided for the management of primary care patients with Type 2 Diabetes Mellitus in Singapore

#### **8. Alternatives to Participation**

If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be the usual care that you have been receiving before. This includes regular visits with doctors, nurses, and dietitians as appropriate.

#### **9. Costs & Payments if Participating in the Study**

If you take part in this study, you will be reimbursed for your time, inconvenience and transportation costs as follows:

- If you complete the first survey administered at the beginning of the study, you will be given a glucometer. The glucometer will not be replaced in the event of lost, stolen, or damaged. No more than four bottles (each with 50 glucose test strips and lancets) will be given to you as needed during the study. If you require additional strips and lancets, you will have to bear the costs for the extra strips and lancets. The glucose test strips and lancets will not be replaced in the event of lost, stolen, or damaged.
- If you complete six months of the study and a second survey, you will be reimbursed with S\$20 cash or equivalent at the sixth month.

- If you complete twelve months of the study and the last survey, you will be reimbursed with S\$30 cash or equivalent at the twelfth month.
- If you did not complete the study for any reason or withdraw from the study, you will not be reimbursed, and you will need to return the glucometer to the study team.

If additional ordering of laboratory tests and/or medications is deemed necessary during your visits with the healthcare team, you will have to bear the costs of the laboratory tests and medications. Participants randomized into the intervention group will not need to bear the additional cost of visiting the clinical pharmacist.

## **10. Voluntary Participation**

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should inform the PI.

If you withdraw from the study, you will be required to inform the PI and return the glucose meter to her or her representative. Refusal to participate or withdrawal from participation will not affect your medical management or cause loss of benefits to which you are otherwise entitled.

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your healthcare providers, the investigators and/or the sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the care team will decide if you may continue in the study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you will be informed in a timely manner by the PI or her representative.

## **11. Compensation for Injury**

If you follow the directions of the health care providers in charge of this study and you are physically injured due to the procedure given under the plan of this study, NHG Pharmacy and NUP will pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your treatment will not be provided by NHG Pharmacy and NUP.

NHG Pharmacy and NUP without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove NHG Pharmacy and/or NUP is/are at fault. There are however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your PI.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

## **12. Confidentiality of Study and Medical Records**

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

However, National University of Singapore, National Healthcare Group Pharmacy, National University Polyclinics, NHG Domain Specific Review Board, and Ministry of Health will be

granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you are authorizing (i) collection, access to, use, and storage of your “Personal Data”, and (ii) disclosure to authorised service providers and relevant third parties.

“Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. This includes medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this “Personal Data”, will be subject to review by the relevant institutional review board.

Data collected and entered into the Case Report Forms are the property of National University of Singapore, National Healthcare Group Pharmacy, and National University Polyclinics. In the event of any publication regarding this study, your identity will remain confidential.

*By participating in this study, you are confirming that you have read, understood and consent to the National University Health System Personal Data Protection Notification available at (<http://www.nuhs.edu.sg/personal-data-protection/nuhsnuh-data-protection-policy.html>) and National Healthcare Group Personal Data Protection Notification available at (<https://corp.nhg.com.sg/Pages/PDPA.aspx>).*

### **13. Who To Contact if You Have Questions**

If you have questions about this study, you may contact the PI.

#### **Overall Principal Investigator**

Ms. Tan Wei Yan Cheryl  
National Healthcare Group Pharmacy  
3 Fusionopolis Link, #05-07  
Nexus@one-north  
Singapore (138543)  
Tel: (65) 9821 0436 / (65) 6516 8014  
Email: cheryl\_wy\_tan@pharmacy.nhg.com.sg

#### **Site Principal Investigator**

Dr. Tsou Yu Kei Keith  
Director  
Clinical Services  
National University Polyclinics  
50 Bukit Batok West Avenue 3  
Singapore (659164)  
Tel: (65) 6496 6773  
Fax: (65) 6566 2208  
Email: keith\_tsou@nuhs.edu.sg

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at [www.research.nhg.com.sg](http://www.research.nhg.com.sg).

If you have any complaints or feedback about this study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

## CONSENT FORM

### Protocol Title:

The Impact of Collaborative Care Model in the Management of Primary Care Patients with Type 2 Diabetes Mellitus in Singapore

### Principal Investigator & Contact Details:

#### Overall Principal Investigator

Ms. Tan Wei Yan Cheryl  
National Healthcare Group Pharmacy  
3 Fusionopolis Link, #05-07  
Nexus@one-north  
Singapore (138543)  
Tel: (65) 9821 0436 / (65) 6516 8014  
Email: cheryl\_wy\_tan@pharmacy.nhg.com.sg

#### Site Principal Investigator

Dr. Tsou Yu Kei Keith  
Director  
Clinical Services  
National University Polyclinics  
50 Bukit Batok West Avenue 3  
Singapore (659164)  
Tel: (65) 6496 6773  
Fax: (65) 6566 2208  
Email: keith\_tsou@nuhs.edu.sg

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction. I have also been informed and understood the alternative treatments or procedures available and their possible benefits and risks.

*By participating in this study, I confirm that I have read, understood and consent to the National University Health System and National Healthcare Group Personal Data Protection Notification.*

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

### Translator Information

The study has been explained to the participant / legally acceptable representative in

\_\_\_\_\_ by \_\_\_\_\_  
(language) (name)

### Witness Statement

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant / the participant's legally acceptable representative signing this informed consent form has the study fully explained in a

language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.

- I have taken reasonable steps to ascertain the identity of the participant / the participant's legally acceptable representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

\_\_\_\_\_  
Name of Witness

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Investigator Statement**

I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his / her participation in the study.

\_\_\_\_\_  
Name of Investigator /  
Person administering consent

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date



## 参加研究同意

研究专目：The Impact of Collaborative Care Model in the Management of Primary Care Patients with Type 2 Diabetes Mellitus in Singapore

您受邀参与上述研究。

在您同意之前，研究者必须告知您以下事项：

- i. 本研究的目的、操作方式和研究时长；
- ii. 任何实验性的操作；
- iii. 任何合理的可预知风险或不适；
- iv. 本研究的任何可能益处；
- v. 任何替代操作或治疗；以及
- vi. 如何维持任何与此研究有关的资料保密性。

如适用，研究者也必须告知您以下事项：

- i. 任何赔偿或药物治疗（如果出现损伤）；
- ii. 不可预知之风险的可能性；
- iii. 研究者可能中止您的参加的情况；
- iv. 您需承担的任何额外费用；
- v. 您决定停止参加后的安排；
- vi. 何时通知您可影响您参与意愿的新发现；以及
- vii. 参与本研究的人数。

如果您同意参与，您必须得到一份经签名的本文件副本以及本研究的一份书面摘要。如有研究相关疑问，您可随时联系 Ms. Tan Wei Yan Cheryl，电话 98210436 / 65160814。

如果您对于您作为研究受试者的权利或在损伤发生后所应采取的措施存有疑问，您可随时联系 Ms. Tan Wei Yan Cheryl，电话 98210436 / 65160814。如果您需要寻求一份对于您研究受试者权利的独立见解，请联系国立健保公司的 Domain Specific Review Board 秘书处，电话：6471-3266。

您是自愿参与本研究的；拒绝参与或决定停止参与将不会给予您任何不利，也不会导致您损失任何利益。

签署本文件即意味着我们已向您口头声明了本研究（包括上述信息），而您自愿同意参与此研究。

\_\_\_\_\_  
参与者姓名

\_\_\_\_\_  
参与者签名

\_\_\_\_\_  
日期

我，身为公正的见证人，证明：

- 我的年龄已满 21 岁。
  - 研究人员已用参与者所能理解的语言对研究进行了充分的解释，并且清楚地解释了参与者参与研究的性质，风险和好处。
  - 我已采取合理的措施来确认参与者的身份。
  - 我已经采取措施确定同意是在没有任何胁迫或恐吓的情况下自愿提供的。
- 我已采取合理的措施来确定同意是在没有任何胁迫或恐吓的情况下自愿提供的。

\_\_\_\_\_  
见证人姓名

\_\_\_\_\_  
见证人签名

\_\_\_\_\_  
日期

\_\_\_\_\_  
研究人员姓名

\_\_\_\_\_  
研究人员签名

\_\_\_\_\_  
日期



OFFICIAL USE ONLY	
Doc Name : Informed Consent Form Template	
Doc Number : 207-001	
Doc Version : 1	Date : 13 Mar 2018

## INFORMED CONSENT FORM

### 1. Study Information

#### Protocol Title:

The Impact of Collaborative Care Model in the Management of Primary Care Patients with Type 2 Diabetes Mellitus in Singapore

#### Principal Investigator & Contact Details:

##### Overall Principal Investigator

Ms. Tan Wei Yan Cheryl  
National Healthcare Group Pharmacy  
3 Fusionopolis Link, #05-07  
Nexus@one-north  
Singapore (138543)  
Tel: (65) 9821 0436 / (65) 6516 8014  
Email: cheryl\_wy\_tan@pharmacy.nhg.com.sg

##### Site Principal Investigator

Dr. Tsou Yu Kei Keith  
Director  
Clinical Services  
National University Polyclinics  
50 Bukit Batok West Avenue 3  
Singapore (659164)  
Tel: (65) 6496 6773  
Fax: (65) 6566 2208  
Email: keith\_tsou@nuhs.edu.sg

#### Study Sponsor:

Health Services Research Competitive Research Grant, Ministry of Health

### 2. Purpose of the Study

You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because you have type 2 diabetes mellitus which can be further improved, and are taking more than five chronic medications.

This study is carried out to find out the added values of collaborative care in helping you improve or achieve the control of your diabetes. Collaborative care involves active participation of clinical pharmacists in managing your diabetes on top of physician's visit.

This study will recruit 250 subjects from multiple institutions under National University Polyclinics (NUP). Each recruited subject will be followed up for a total of 1 year.

### 3. What procedures will be followed in this study

If you take part in this study, you will be randomized into two groups (refer to Table 1). Randomization means assigning you to one of the two groups by chance, like computerized assignment using opaque, sealed envelopes.

This study is twelve-month in length. If you take part in this study, you will be asked to answer a survey of about 45 minutes at the beginning of the study, at six months, and at twelve months (total time spent will be around 2 hours 30 minutes), administered by the Principal Investigator (PI) or her representative, at the beginning of the study, at six months, and at twelve months of the study. The survey consists of the following:

- Quality of life
- Diabetes distress
- Treatment satisfaction
- Self-care
- Productivity
- Hypoglycaemia

In addition, information about your laboratory tests and medications will also be extracted only for the purpose of this study and the representative may also call you for care- and administrative-related matters if needed.

If you are invited to see a healthcare team with a pharmacist for your diabetes care, you will also be asked to follow up with the team and follow their instructions. Some may require telephone-counselling, but most of the visits will be face-to-face. The healthcare team may provide:

- Counselling on medication therapy, self-care practices, exercise, and diet
- Modify medication dose and frequency
- Perform simple physical assessment, e.g. measure blood pressure, assess for swelling, etc.
- Order follow-up visits with the healthcare providers
- Order laboratory tests as appropriate

You will still be continuing with your regular visits to the doctor at least every 4-monthly.

If you agree to take part in this study, you will be randomized into one of the following groups:

**Table 1: Description of randomised groups**

	Group A: Usual care	Group B: Visit a healthcare team with involvement of a pharmacist
Care	Routine care with doctor as usual, and referral to nurse and/or dietitian as needed (number of visits are based on the need determined by your doctor)	Routine care with a healthcare team of doctors, nurses, and/or dietitians, (number of visits are based on the need determined by your healthcare team)  <u>AND</u> Visits with pharmacist at least every four to six weeks (face-to-face or via phone call).
Extracting information	Yes (from electronic medical records) <ul style="list-style-type: none"> <li>• Laboratory tests, medical history, medication list, cost</li> </ul>	Yes (from electronic medical records) <ul style="list-style-type: none"> <li>• Laboratory tests, medical history, medication list, cost</li> </ul>
Answering questionnaires	At the beginning At sixth month At twelfth month	At the beginning At sixth month At twelfth month

#### **4. Your Responsibilities in This Study**

If you agree to participate in this study, you should follow the advice given to you by the study team. You should be prepared to visit the hospital or polyclinics regularly as instructed by your healthcare providers (doctors, nurses, dietitians, and pharmacists as appropriate) and undergo all necessary procedures, including those outlined in Table 1.

#### **5. What Is Not Standard Care or is Experimental in This Study**

The study is being conducted because the collaborative care model is not yet proven to be a standard practice model in subjects with type 2 diabetes in Singapore. We hope that your participation will help us to determine whether a team-based care can add value to the current practice model.

Your health care providers will be informed about your participation in the study. However, they will not know which group you belong to. Only the study team knows which group you have been randomized to.

Although this care model may be part of standard medical care, in this study the involvement of pharmacists in the team is only being performed for the purposes of the research, and it is not part of your routine care. The administration and completion of the questionnaires are not part of your standard medical care and are conducted for research purposes only.

#### **6. Possible Risks and Side Effects**

There are minimal to no possible risks or side effects for participating in this study, except for a highly unlikely but potential risk of breach of confidentiality. As the collaborative care is to provide an added value, your standard of care or routine care is still being preserved. At any point in time, if you feel uncomfortable in answering the survey, you may stop and withdraw from the survey or session.

#### **7. Possible Benefits from Participating in the Study**

There is no assurance you will benefit from participation in this study. However, your participation in this study may add to the general knowledge to improve the care provided for the management of primary care patients with Type 2 Diabetes Mellitus in Singapore.

#### **8. Alternatives to Participation**

If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be the usual care that you have been receiving before. This includes regular visits with doctors, nurses, and dietitians as appropriate.

#### **9. Costs & Payments if Participating in the Study**

If you take part in this study, you will be reimbursed for your time, inconvenience and transportation costs as follows:

- If you complete the first survey administered at the beginning of the study, you will be given a glucometer. The glucometer will not be replaced in the event of lost, stolen, or damaged. No more than four bottles (each with 50 glucose test strips and lancets) will be given to you as needed during the study. If you require additional strips and lancets, you will have to bear the costs for the extra strips and lancets. The glucose test strips and lancets will not be replaced in the event of lost, stolen, or damaged.
- If you complete six months of the study and a second survey, you will be reimbursed with S\$20 cash or equivalent at the sixth month.

- If you complete twelve months of the study and the last survey, you will be reimbursed with S\$30 cash or equivalent at the twelfth month.
- If you did not complete the study for any reason or withdraw from the study, you will not be reimbursed, and you will need to return the glucometer to the study team.

If additional ordering of laboratory tests and/or medications is deemed necessary during your visits with the healthcare team, you will have to bear the costs of the laboratory tests and medications. Participants randomized into the intervention group will not need to bear the additional cost of visiting the clinical pharmacist.

## **10. Voluntary Participation**

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should inform the PI.

If you withdraw from the study, you will be required to inform the PI and return the glucose meter to her or her representative. Refusal to participate or withdrawal from participation will not affect your medical management or cause loss of benefits to which you are otherwise entitled.

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your healthcare providers, the investigators and/or the sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the care team will decide if you may continue in the study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you will be informed in a timely manner by the PI or her representative.

## **11. Compensation for Injury**

If you follow the directions of the health care providers in charge of this study and you are physically injured due to the procedure given under the plan of this study, NHG Pharmacy and NUP will pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your treatment will not be provided by NHG Pharmacy and NUP.

NHG Pharmacy and NUP without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove NHG Pharmacy and/or NUP is/are at fault. There are however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your PI.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

## **12. Confidentiality of Study and Medical Records**

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

However, National University of Singapore, National Healthcare Group Pharmacy, National University Polyclinics, NHG Domain Specific Review Board, and Ministry of Health will be

granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you are authorizing (i) collection, access to, use, and storage of your “Personal Data”, and (ii) disclosure to authorised service providers and relevant third parties.

“Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. This includes medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this “Personal Data”, will be subject to review by the relevant institutional review board.

Data collected and entered into the Case Report Forms are the property of National University of Singapore, National Healthcare Group Pharmacy, and National University Polyclinics. In the event of any publication regarding this study, your identity will remain confidential.

*By participating in this study, you are confirming that you have read, understood and consent to the National University Health System Personal Data Protection Notification available at (<http://www.nuhs.edu.sg/personal-data-protection/nuhsnuh-data-protection-policy.html>) and National Healthcare Group Personal Data Protection Notification available at (<https://corp.nhg.com.sg/Pages/PDPA.aspx>).*

### **13. Who To Contact if You Have Questions**

If you have questions about this study, you may contact the PI.

#### **Overall Principal Investigator**

Ms. Tan Wei Yan Cheryl  
National Healthcare Group Pharmacy  
3 Fusionopolis Link, #05-07  
Nexus@one-north  
Singapore (138543)  
Tel: (65) 9821 0436 / (65) 6516 8014  
Email: cheryl\_wy\_tan@pharmacy.nhg.com.sg

#### **Site Principal Investigator**

Dr. Tsou Yu Kei Keith  
Director  
Clinical Services  
National University Polyclinics  
50 Bukit Batok West Avenue 3  
Singapore (659164)  
Tel: (65) 6496 6773  
Fax: (65) 6566 2208  
Email: keith\_tsou@nuhs.edu.sg

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at [www.research.nhg.com.sg](http://www.research.nhg.com.sg).

If you have any complaints or feedback about this study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.



## CONSENT FORM

### Protocol Title:

The Impact of Collaborative Care Model in the Management of Primary Care Patients with Type 2 Diabetes Mellitus in Singapore

### Principal Investigator & Contact Details:

#### Overall Principal Investigator

Ms. Tan Wei Yan Cheryl  
National Healthcare Group Pharmacy  
3 Fusionopolis Link, #05-07  
Nexus@one-north  
Singapore (138543)  
Tel: (65) 9821 0436 / (65) 6516 8014  
Email: cheryl\_wy\_tan@pharmacy.nhg.com.sg

#### Site Principal Investigator

Dr. Tsou Yu Kei Keith  
Director  
Clinical Services  
National University Polyclinics  
50 Bukit Batok West Avenue 3  
Singapore (659164)  
Tel: (65) 6496 6773  
Fax: (65) 6566 2208  
Email: keith\_tsou@nuhs.edu.sg

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction. I have also been informed and understood the alternative treatments or procedures available and their possible benefits and risks.

*By participating in this study, I confirm that I have read, understood and consent to the National University Health System and National Healthcare Group Personal Data Protection Notification.*

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

### Translator Information

The study has been explained to the participant / legally acceptable representative in

\_\_\_\_\_ by \_\_\_\_\_  
(language) (name)

### Witness Statement

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant / the participant's legally acceptable representative signing this informed consent form has the study fully explained in a



## **Kebenaran untuk Menyertai Penyelidikan**

Tajuk Kajian: The Impact of Collaborative Care Model in the Management of Primary Care Patients with Type 2 Diabetes Mellitus in Singapore

Anda dipelawa untuk menyertai kajian penyelidikan di atas.

Sebelum anda bersetuju, penyelidik mesti memaklumkan kepada anda mengenai:

- i. tujuan, prosedur, dan tempoh penyelidikan;
- ii. sebarang prosedur yang dianggap percubaan;
- iii. sebarang risiko atau ketidakselesaan yang diduga;
- iv. sebarang faedah penyelidikan yang mungkin diperolehi;
- v. sebarang prosedur atau rawatan alternatif; dan
- vi. bagaimana kerahsiaan akan dipelihara.

Di mana sesuai, penyelidik juga mesti memaklumkan kepada anda mengenai:

- i. sebarang pampasan atau rawatan perubatan yang ada jika berlaku kecederaan;
- ii. kemungkinan berlakunya risiko yang tidak diduga;
- iii. keadaan-keadaan di mana penyelidik mungkin akan menghentikan penyertaan anda;
- iv. sebarang kos tambahan yang harus ditanggung oleh anda;
- v. apa yang akan berlaku sekiranya anda memutuskan untuk menghentikan penyertaan;
- vi. apabila anda diberitahu mengenai dapatan baru yang mungkin akan menjejaskan kesanggupan anda untuk mengambil bahagian; dan
- vii. berapa ramai orang akan menyertai kajian ini.

Jika anda bersetuju untuk mengambil bahagian, anda mesti menerima satu salinan dokumen yang telah ditandatangani dan ringkasan bertulis mengenai penyelidikan ini.

Jika anda mempunyai soalan mengenai penyelidikan ini, anda boleh menghubungi Penyelidik Utama, Ms. Tan Wei Yan Cheryl di 98210436 / 65168014 pada bila-bila masa sekiranya anda mempunyai soalan mengenai penyelidikan ini.

Anda boleh menghubungi Ms. Tan Wei Yan Cheryl di 98210436 / 65168014 sekiranya berlaku sebarang kecederaan terhadap diri anda sewaktu penyelidikan ini dijalankan.

Jika anda ingin pendapat bebas mengenai hak anda sebagai subjek dalam kajian ini, anda boleh menghubungi sekretariat NHG Domain Specific Review Board di 6471-3266. Penyertaan anda dalam penyelidikan ini adalah secara sukarela, dan anda tidak akan didenda atau kehilangan faedah sekiranya anda enggan mengambil bahagian atau memutuskan untuk berhenti. Menandatangani dokumen ini bermakna bahawa kajian penyelidikan ini, termasuk maklumat di atas telah diterangkan kepada anda secara lisan, dan anda secara sukarela bersetuju untuk menyertainya.

\_\_\_\_\_  
Nama Peserta

\_\_\_\_\_  
Tandatangan Peserta

\_\_\_\_\_  
Tarikh

Saya, yang menandatangani, sahkan bahawa:

- Saya berumur 21 tahun and ke atas.
- Pada pengetahuan terbaik saya, peserta / wakil peserta yang sah di sisi undang-undang, yang menandatangani borang keizinan ini telah menerima penerangan sepenuhnya dalam bahasa yang difahami peserta dan memahami secara jelas sifat, risiko, dan manfaat semasa menyertai kajian.
- Saya telah mengambil langkah-langkah yang munasabah untuk pastikan identiti

- peserta / wakil peserta yang sah di sisi undang-undang yang memberi keizinan.
- Saya telah mengambil langkah-langkah untuk pastikan bahawa keizinan telah diberikan secara sukarela tanpa sebarang paksaan atau intimidasi.

_____ Nama Saksi	_____ Tandatangan Saksi	_____ Tarikh
---------------------	----------------------------	-----------------

_____ Nama Penyelidik / Orang yang Mentadbir Kebenaran	_____ Tandatangan Orang yang Mentadbir Kebenaran	_____ Tarikh
--	--	-----------------