**Consent/Assent for Participation in a Research Project (For people with diagnosed T2DM)**
**Explanatory Statement**

**Study Title: "Community-based lifestyle intervention for diabetes management in Nepal: A Cluster randomized trial."**

**Name of the organization conducting the study:** Dhulikhel Hospital Kathmandu University Hospital

**Principal Investigator:** Dr. Abha Shrestha (Department of Community Program, Dhulikhel Hospital, Kathmandu University Hospital)

**Co- Investigators:** Dr. Biraj M Karmacharya (Department of Community Program), Dr. Archana Shrestha (Department of Community Program), Mr. Prabin Shakya (Department of Community Program).

**Description of Study Population**: Clinically diagnosed type 2 diabetes of adult age group including 30-60 years.

**Version Date**: April 2019

Dear Madam/Sir,

We are carrying out a study to develop low-cost culturally appropriate and locally tailored diabetes lifestyle modification intervention program for diabetes management for people with T2DM. The study is funded by Global Alliance for Chronic Disease (GACD) and Japan Agency for Medical Research and Development (AMED) under the official contract between Tokyo Women's Medical University (TWMU) and AMED and conducted in collaboration with Department of International Affairs and Tropical Medicine, Tokyo Women's Medical University, Japan and Dhulikhel Hospital Kathmandu University Hospital, Nepal. The purpose of this study is to test whether the diabetes self-management support program activities given by trained community health workers and peer supports will effect in reducing blood glucose among individual with diabetes. The study is being conducted in rural village council of Kavrepalanchowk and Nuwakot districts of Nepal. This is a prospective, community-based, single blinded end-point assessment, 2-arm randomized controlled trial. We will select total 576 participants from 32 clusters i.e 18 participants from each 32 cluster (1 cluster=18 participants) through i) Reviewing the available health registries in Government health service centers, private health centers, and Dhulikhel Hospital outreach centers, ii) Organizing screening camps and iii) household survey of designated study site.

**Why is this study important?**

The study aims to develop a culturally tailored and locally contextual diabetes lifestyle modification intervention training program for community health workers. We are trying to find out that if promoting diabetes self- management support program activities then, will it be help in reducing blood glucose among individuals with diabetes or not. This is important because diabetes prevalence in Nepal is high and people thought that once the diabetes is found then medicine should be taken throughout the life. It can't be controlled. There are no world community –based implementation trial of a lifestyle intervention targeting the adults with T2DM in rural Nepal So, We also trying to examine the real-world implementation challenges which will help to facilitators for implementation, adoption and scaling up of community based diabetes management and care programs in other parts of Nepal and beyond. The findings from the research are going to feed directly to policy and long-term government's plans and strategies for NCDs prevention and management in Nepal.

**Why have you been chosen to take part in this study?**

We will invite you to take part in this implementation science research study to see if people with diagnosed T2DM are given appropriate group based lifestyle intervention for improving management and care of T2DM then what will be the result in reducing blood glucose among individual with diabetes. All of the participants from selected clusters will be placed in one of the two group by random allocation as intervention and control group. In the intervention group, participants will receive educational sessions on lifestyle modification by trained community health workers and trained peer leaders will support throughout the intervention period to ensure adoption and maintenance of healthy behavior such as regular physical activity, healthy food, no smoking, and use of health care services when needed. The control group will receive the usual care with no lifestyle intervention by CHWs and the peer support groups. However, they will receive the pictorial brochure on diabetes prevention education in Nepali language in order not to deprive them from awareness.

**Voluntary Participation**

It is entirely your decision to participate in the study. If you want to discontinue at any point of time of the study you are free to leave without stating any reason. You have the right to ask any questions concerning the study any time during the interview.

**What information will be collected from me and how? What will happen to me if I take part in this study?**

If you take part in this research you will be contacted by the research assistants at baseline, 6 month and 12 months. We will prick your blood for the test of HbA1c and measured your height, weight, blood pressure, waist and hip measurements. If you meet the criteria (age group 30-60 years and Hb1Ac $\geq$6.5%), you will be asked to fill the survey questionnaire. The questionnaires include socio-demographic variables such as; age (years), sex (male/female), ethnicity, education

(number of year of formal education), occupation, per capita household income, behavioral; smoking (pack year of smoking), alcohol consumption(number of drink per week) physical activity and anthropometric measures; body weight (kg), height (meters), waist circumference (cm), hip circumference (cm), BMI (kg/m2), and other variables such as blood pressure, diabetes , food habit, quality of life, diabetes distress, depression, health care utilization etc. We will ask you to continue to take part in the study for next 12 months. You will be asked to let us draw your blood sample in midline (6 month) and end line (12 month). In baseline, all of the participants from selected clusters will be placed in one of the two group by random allocation as intervention and control group. The intervention group will receive the group-based sessions for the self-management of diabetes including determining high risk signs and symptoms of diabetes by the trained community health workers and motivated peer supporters who will be selected among the diabetes participants. They will work closely with the trained CHWs and facilitate the group-based sessions. The second group will also receive the pictorial brochure on diabetes prevention education but not lifestyle intervention by CHWs and the peer support groups.

This tool would not be used to judge your knowledge, but would only be used to help us to examine the real world implementation challenges which will help to facilities for implantation, adoption and scaling up of community based diabetes management and care programs in other parts of Nepal and beyond. The information you give us will be only seen by the research team, trained health workers and peer supporters who are working on this project – and maybe some other researchers who are interested in what is happening in Nepal. We will not show your answers to any other health workers who is not involving in this research or other people working in this area. Confidentiality will be maintained by numerically coding data, by disguising identifying information, and by keeping all data in locked file drawers. All information obtained from subjects will be accessible only to research staff. All staff will be trained in confidentiality procedures, and routine refreshers provided. We will put the answers into a password protected computer. When the results are published in research journals or discussed with relevant stakeholders, your names and details will not be disclosed.

The interview will take up to 60 minutes.

**What are the possible disadvantages/ risks of taking part?**

We do not expect that your participation will bring you any harm. We will use disposable finger prick under hygienic conditions. During the blood draws, your will feel a slight prick. Bruising and infection are a possibility, but not very likely. Time to respond to the questionnaires may be an inconvenience. But, we will not ask you any sensitive questions. Some questions might be uncomfortable to answer. You do not have to answer any questions that make you uncomfortable. We do not think there are any other risks to you participating in the study because we will keep the answers that you give us confidential and only the researchers will know about it. We will not share any information you share with us or any notes of what we observe with other participants and colleagues. We will keep all the information that you give us in a special password-protected computer and in locked offices at the universities and organizations where we work. We will keep your personal details in a different place from where we keep the answers that you give us. When we write up the study, we will not use your name, or the name of the village or health care facility where we did the research.

**How will I benefit from this study? OR What are the possible benefits of taking part?**

There are no benefits to you for participation in this research and we cannot pay you for participating. However, if you agree to participate in the study and you are having type 2 diabetes, you will receive free diabetes screening in six months and 12 month, you will have training on self-monitoring of diabetes including determining high risk signs and symptoms by trained CHWs and peer supporters and you may receive educational sessions for diabetes self-management. The information obtained through this study will potentially benefit other Diabetes population of the world where there is high diabetes prevalence and also the information obtained from the study will lead to an efficient intervention the ongoing and long-term government's plans and strategies for NCDs prevention and management in Nepal.

**Will I be informed about the results of this study?**

The findings from this study will be expected to feed directly to policy on design and implementation of effective, culturally appropriate, contextual and community based intervention for the effective management of T2DM. We will also develop a report which will highlight the reducing blood glucose level by promoting diabetes self- management support program activities and inform you as well.

**Will I be given a copy of this information sheet?**

Yes, you will be provided with a copy of this participant information sheet to keep with you. You are free to discuss this with anyone you wish to consult.

**Who can I contact for additional information?**

- If you have additional questions about the study at any point in time, please contact the Principal Investigator Dr. Abha Shrestha (Department of Community Program Ph no. 9801315233) / Co- Investigators Dr. Biraj M Karmacharya (Department of Community Program Ph no. 9802000029) / Project Co-ordinator Dr. Samikshya Neupane (Department of Community Program Ph no. 9861156536) / Project Officer Ms. Deepa Laxmi Makaju (Department of Community Program Ph no. 9849376373) at Dhulikhel Hospital
- Nepal Health Research Council (NHRC)
  P.O. Box: 7626, Ramshah Path, Kathmandu, Nepal
  Tel: +977-1-4254220, 4227460
  E-mail: nhrc@nhrc.org.np

Thank you for taking the time to read this information. We appreciate your participation in this research. The interview will only be conducted once you have asked any other questions that you may have and have signed the relevant consent forms. You can keep this information sheet with you.

**Agreement to Participate:**
I have read the above information, have had the opportunity to have any questions about this study answered and agree to participate in this study.

_____ _____
(Printed name) (Date)

_____
(Signature)

_____ _____
Signature of Person Obtaining Consent Date

**SIGNATURE**
Printed name of person obtaining consent and assent
My signature and date indicates that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally authorized representative, and that informed consent was freely given by the participant or the legally authorized representative.

**Consent/Assent for CHWs**

**Study Title: "Community-based lifestyle intervention for diabetes management in Nepal: A Cluster randomized trial."**

**Please tick all boxes that apply:**

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| 1 | I have been given the information sheet about the study and had it explained to me. | |
| 2 | I agree to participate in 12 monthly peer group sessions over a duration of 12 months | |
| 3 | I agree to allow the research team to provide updates on my progress to the primary care provider that I nominate as required | |
| 4 | I agree to allow the research team to access relevant information from my hospital medical records and primary carer for the 12 month period in which I am enrolled in this study | |
| 5 | I agree to visit a local facility for measurements at the start of the study and for follow up measurements at 6, 12 months after my enrolment in the study | |
| 6 | I agree to be contacted to participate in related research studies in the future. I understand that I am not obliged to agree to participate. | |
| 7 | I know who to contact if I have any more questions after the interview or if I am unhappy with how the researcher has behaved. | |
| 8 | I understand that I do not have to be interviewed, and I can stop the interview at any time and do not need to give a reason. | |
| 9 | I understand that all the information I give will be kept private and answers that I give will not be shared with my manager, colleagues or other health workers. | |
| 10 | I understand I will not be paid for this interview and that agreeing to be interviewed or any of the information that I give won't affect my work or supervision at this facility. | |
| 11 | I agree for the interview to be audio recorded. | |
| 12 | I agree for the researchers to use what I tell them in reports, articles and other work that they write, and understand that my name or the name of the health facility, village or local area will not be used in the report. | |
| 13 | I understand that the information that I give in the interview might be given to other researchers who are working to develop a community based diabetes management and care programs in other parts of Nepal but they will not be given my name or the name of the health facility, village or local area. | |

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| 14 | By signing this form, I give my free and informed consent to take part in this study as outlined in the information sheet and this consent form. | |

**Agreement to Participate:**
I have read the above information, have had the opportunity to have any questions about this study answered and agree to participate in this study.

_____ _____
(Printed name) (Date)

_____
(Signature)

_____ _____
Signature of Person Obtaining Consent Date

**SIGNATURE**
Printed name of person obtaining consent and assent
My signature and date indicates that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally authorized representative, and that informed consent was freely given by the participant or the legally authorized representative.

**Consent/Assent for Peer Leaders**

**Study Title: "Community-based lifestyle intervention for diabetes management in Nepal: A Cluster randomized trial."**

**Please tick all boxes that apply:**

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|---|---|---|
| 1 | I have been given the information sheet about the study and had it explained to me. | |
| 2 | I agree to attend a 3-day training program for Peer Leaders. | |
| 3 | I agree to facilitate monthly support groups for 12 months for people with type 2 diabetes as described in the training program for Peer Leaders | |
| 4 | I agree to provide peer support and relevant information to participants in the group program as described in the training program for Peer Leaders | |
| 5 | I agree to work collaboratively with group participants, community organizations and health workers who are linked to the Peers for Progress project | |
| 6 | I agree to inform, encourage, and support individual members of the group program to access health professionals as described in the training program for Peer Leaders. | |
| 7 | I agree to maintain a record of activities undertaken and discussed during the monthly support group meetings | |
| 8 | I agree to maintain confidentiality of all information provided to me by and about group participants, Peer Leaders, and others linked to the Peers for Progress project | |
| 9 | I agree to participate in all practice training, debriefing sessions and meetings as scheduled by the Peers for Progress Project Manager, which may be recorded for study purposes | |
| 10 | I agree to collect information about group attendance and other record keeping duties as described by the Peers for Progress Project Manager | |
| 11 | I agree to be contacted to participate in related research studies in the future. I understand that I am not obliged to agree to participate. | |
| 12 | I agree to provide an alternative contact number (friend or relative) who will know I am involved in this study and will agree to enable contact between myself and the researchers | |
| 13 | I agree to participate in this study by doing my signature in this form. | |

**Agreement to Participate:**

I have read the above information, have had the opportunity to have any questions about this study answered and agree to participate in this study.

_____ _____

(Printed name) (Date)

_____

(Signature)

_____ _____

Signature of Person Obtaining Consent Date

**SIGNATURE**

Printed name of person obtaining consent and assent

My signature and date indicates that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally authorized representative, and that informed consent was freely given by the participant or the legally authorized representative.

## सु सुचित सहमति फारम

## सामुदायिक स्वास्थ्य कार्यकर्ताको लागि सु सुचित सहमति फारम

**अध्ययन शीर्षक: "नेपालमा मधुमेह व्यवस्थापनको लागि समुदायमा-आधारित जीवनशैली ईन्टरभेन्सन कार्यक्रम: एक क्लस्टर रानडमाइज ट्रयाल ।"**

**कृपया लागू हुने सबै बक्सहरूमा टिक लगाउनु होस्।**

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| १ | मलाई यस अध्ययनको बारेमा राम्रो संग सूचना दिई व्यख्या गराईएको छ। | |
| २ | मलाई थाहा छ कि मैले १२ महिनाको अवधिसम्म मासिक १२ पटक साथी समूह सेसनहरूमा भाग लिनुपर्ने छ। | |
| ३ | मलाई थाहा छ कि आवश्यकताको आधारमा प्राथमिक हेरचाह प्रदायकको लागि मेरो नाम नमोनित भएको हैसियत् ले मैले दिएको योगदान र मेरो प्रगतिको बारेमा अद्यावधिक जानकारी प्रदान गर्न रिसर्च अनुसन्धान टोलीलाई अनुमति दिनु हुनेछ। | |
| ४ | मलाई थाहा छ कि यस अध्ययनमा भर्ना भएपछि मैले स्थानीय संकायमा गएर मापन गर्नुपर्ने र अध्ययनकै क्रममा फेरी अर्को ६ महिना र १२ महिनामा पनि मापनका लागि स्थानीय संकायमा भ्रमण गर्नुपर्ने छ। | |
| ५ | मलाई थाहा छ कि भविष्यमा सम्बन्धित अनुसन्धान अध्ययनहरूमा भाग लिन मलाई सम्पर्क गर्नुहुनेछ जहाँ म सहमत हुन बाध्य हुनेछैन। | |
| ६ | यदी यो अन्तर्वाता पछी मेरो केही प्रशनहरु छन् भने अथवा म अनुसन्धान कर्ताको व्यवहारबाट खुसी नभएमा कसलाई सम्पर्क गर्ने हो भन्ने बारे थाहा छ। | |
| ७ | मलाई थाहा छ कि म कुनै पनि बेलामा अन्तर्वाता छोड्न सक्छु र मलाई त्यसको कारण दिन आवश्यक छैन। | |

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| ८ | मलाई थाहा छ कि मैले दिएको सबै जानकारीहरु गोप्य राखिनेछ र मेरो जवाफहरु कुनै पनि व्यवस्थापक, सहकर्मीहरु वा अन्य स्वास्थ्य कर्मीहरुलाई दिईने छैन । | |
| ९ | मलाई थाहा छ कि यस अन्तर्वाता को लागि मलाई कुनै पनि रकम दिईने छैन र म यसको लागि सहमत छु र मैले दिएको जानकारीले यस संस्था मा र मेरो काममा केही पनि असर गर्ने छैन । | |
| १० | म अन्तर्वाता को लागि अडीयो रेकर्ड गर्न सहमत छु । | |
| ११ | मैले दिएको सूचना अनुसन्धानकर्ताहरुले प्रकाशन गरिने रिपोर्ट, लेख र अन्य सूचना कार्यहरुमा प्रयोग गर्नको लागि सहमत छु र यसमा मेरो नाम, स्वास्थ्य संस्था, गाउँ वा स्थानीय क्षेत्र गोप्य राखिनेछ भन्ने बिषयमा ज्ञात छु । | |
| १२ | मैले बुझे कि मैले दिएको जानकारी अन्य अनुसन्धानकर्ताहरूलाई दिईनेछ जसले नेपालको अन्य भागमा समुदाय आधारित मधुमेह व्यवस्थापन गर्नको लागि काम गरिरहेका छन् तर तिनीहरूले मेरो नाम, स्वास्थ्य संस्था, गाउँ वा स्थानीय क्षेत्र गोप्य राखिनेछ भन्ने बिषयमा ज्ञात छु| | |
| १३ | यस फारममा हस्ताक्षर गरेर म यस अध्ययनमा भाग लिन सु- सुचित सहमति दिन्छु । | |

अनुसन्धानको बिषयमा मैले चाहेको कुनै पनि प्रश्नहरु सोध्न र मेरो सबै प्रश्नहरुको जवाफ दिईएको छ र म यस अध्ययनमा भाग लिन सु- सुचित सहमति दिन्छु|

सहभागी

नाम (देवनागरीमा )

हस्ताक्षर: मिति:

यदी माथि उल्लेखित सबै बुंदाहरुमा तपाइको सहमति छ कृपया यसमा हस्ताक्षर गर्नु होस् |

हस्ताक्षर मिति:

( चेकलिस्टमा भएको सबै कुरामा सहमत छु भने कृपया यसमा हस्ताक्षर गर्नु होस् |)

## सु सुचित सहमति फारम

## साथी नेतृत्वको लागि सु सुचित सहमति फारम

**अध्ययन शीर्षक:"नेपालमा मधुमेह व्यवस्थापनको लागि समुदायमा-आधारित जीवनशैली ईन्टरभेन्सन कार्यक्रम: एक क्लस्टर रानडमाइज ट्रयाल ।"**

**कृपया लागू हुने सबै बक्सहरूमा टिक लगाउनु होस् ।**

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| १ | मलाई यस अध्ययनको बारेमा राम्रो संग सूचना दिई व्यख्या गराईएको छ। | |
| २ | मलाई थाहा छ कि साथी नेतृत्वको लागि चयन भएपछी मैले ३ दिने प्रशिक्षण कार्यक्रममा भाग लिनुपर्नेछ। | |
| ३ | मलाई थाहा छ कि साथी नेतृत्वको प्रशिक्षण कार्यक्रममा वर्णन गरिए अनुसार टाइप २ मधुमेह भएका व्यक्तिहरूको लागि मैले १२ महिना सम्म सुविधा दिनका लागि मासिक समर्थन समूहहरू बनाउनु पर्नेछ। | |
| ४ | मलाई थाहा छ कि साथी नेतृत्वको प्रशिक्षण कार्यक्रममा वर्णन गरिए अनुसार मैले समूह कार्यक्रममा सहभागीहरूलाई साथी भई सहयोग र समर्थन गरी सान्दर्भिक जानकारी प्रदान गर्नुपर्नेछ। | |
| ५ | मलाई थाहा छ कि मैले समुहका सहभागीहरू, सामुदायिक संगठनहरू र स्वास्थ्यकर्मीहरूसँग मिलेर काम गर्नुपर्नेछ जो प्रगति परियोजनाको साथीहरूको साथ जोडिएका छन्। | |
| ६ | मलाई थाहा छ कि यस अध्ययनमा भर्ना भएपछि मैले साथी नेतृत्वको प्रशिक्षण कार्यक्रममा वर्णन गरिए अनुसार स्वास्थ्य सम्भन्धित सान्दर्भिक जानकारी प्राप्त गर्न का लागि समूह कार्यक्रमका प्रत्येक सदस्यलाई जानकारी प्रोत्साहित र समर्थन गर्नुपर्नेछ। | |
| ७ | मलाई थाहा छ कि मैले मासिक समर्थन समूह बैठकहरूको समयमा गरिएको छलफल र गतिविधिहरूको रेकर्ड राख्नुपर्नेछ। | |
| ८ | मलाई थाहा छ कि मैले दिएको सबै जानकारीहरु गोप्य राखिनेछ र अन्य सम्बन्धित जानकारी पनि जस्तै समुहमा सहभागीता, साथी नेतृत्व र प्रगति परियोजनाका लागि साथीहरूको साथ आदी। | |

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| ९ | मलाई थाहा छ कि प्रोजेक्ट प्रबन्धकले बनाएका तालिका अनुसार मैले सबै अभ्यासहरु सिकाउने ट्रेनिङहरु, संक्षिप्त रुप्मा वर्णन गरिने सेसनहरू र बैठकहरुमा भाग लिनुपर्नेछ, जुन अध्ययन उद्देश्यका लागि रेकर्ड हुन सक्छ। | |
| १० | मलाई थाहा छ कि प्रोजेक्ट प्रबन्धकले बनाएका तालिका अनुसार मैले समूहमा उपस्थिति हुन रेकर्ड र अन्य रेकर्ड राख्ने र जानकारी सकलन गर्नुपर्नेछ| | |
| ११ | मलाई थाहा छ कि भविष्यमा सम्बन्धित अनुसन्धान अध्ययनहरूमा भाग लिन मलाई सम्पर्क गर्नुहुनेछ जहाँ म सहमत हुन बाध्य हुनेछैन| | |
| १२ | म आफ्नो कुनै अर्को वैकल्पिक सम्पर्क नम्बर (मित्र वा आफन्तको) प्रदान गर्न सहमत छु जसले गर्दा म यस अध्ययनमा संलग्न रहेको थाहा हुन्छ र आपत्कालिन अवस्थामा यी सम्पर्क नम्बरमा सम्पर्क गरी मेरो र अनुसन्धानकर्ताहरू बीच सम्पर्क राख्न सजिलो हुन्छ| | |
| १३ | यस फारममा हस्ताक्षर गरेर म यस अध्ययनमा भाग लिन सु- सुचित सहमति दिन्छु । | |

अनुसन्धानको बिषयमा मैले चाहेको कुनै पनि प्रश्नहरु सोध्न र मेरो सबै प्रश्नहरुको जवाफ दिईएको छ र म यस अध्ययनमा भाग लिन सु- सुचित सहमति दिन्छु|

सहभागी

नाम (देवनागरीमा )

हस्ताक्षर: मिति:

यदि माथि उल्लेखित सबै बुंदाहरुमा तपाईको सहमति छ भने कृपया यसमा हस्ताक्षर गर्नुहोस् |

हस्ताक्षर मिति:

( चेकलिस्टमा भएको सबै कुरामा सहमत छु भने कृपया यसमा हस्ताक्षर गर्नुहोस् |)