College/Faculty/Branch/Cluster of Centre of Excellence Universiti Teknologi MARA

Ethics Approval Application Form for Undergraduates or Masters by Coursework

Borang Permohonan Kelulusan Etika bagi Pelajar Sarjana Muda atau Sarjana Kerja Kursus

This application is for the purpose of obtaining approval to conduct research. Please attach a copy of Research Proposal.

Permohonan ini dikemukakan untuk tujuan kelulusan menjalankan penyelidikan. Sila lampirkan salinan kertas cadangan penyelidikan.

The submission of this form should be at least TWO (2) months before the expected date of initial data collection.

Penyerahan borang ini hendaklah sekurang-kurangnya DUA (2) bulan sebelum tarikh jangkaan pengumpulan data awal.

Part A : Details of Researcher

Bahagian A: Maklumat Penyelidik

Title of Research Project :
Tajuk Penyelidikan : The Effect of Very Low Carbohydrate diet on Anthropometric measure and insulin resistance in Prediabetes and Obesity

Name of Researcher* :
Nama Penyelidik* Nur Adila binti Muhammad Zawawi

Name of Supervisor(s) :
Nama Penyelia
Prof . Dr Rohana Abd Ghani
Dr Nur Aini Eddy Warman
Dr Chen Xin Wee

Address of Department/ Institute :
Alamat Jabatan/ Institut : Faculty of Medicine, University Teknologi MARA, Sungai Buloh Campus, Selangor Branch, 47000, Jalan Hospital, Sungai Buloh, Selangor, Malaysia

Contact No/ Email :
No.Telefon/ Emel : 012-6522611/ 2023459656@student.uitm.edu.my

☐ Undergraduate / Sarjana Muda

☑ Masters by Coursework/ Sarjana Kerja Kursus

Nama program pengajian:

Study programme name: Master of Internal Medicine

Does the research require external Research Ethics Committee approval? (e.g. MREC) Adakah penyelidikan ini memerlukan kelulusan Jawatankuasa Etika Penyelidikan Luaran? (contoh MREC)	
☐ Yes / Ya √ ~~No~~ / Tidak ☐	External Committee Name:

Research funding: Yes

Dana Penyelidikan: Ada

If YES, please complete section C.

Jika ada, sila lengkapkan bahagian C.

Part B : Research Details

Bahagian B: Maklumat Penyelidikan

Part B1
Bahagian B1

☐ Interviews Temubual Focus groups Kumpulan focus	☐ Case study Kajian kes Intervention study
☐ Questionnaires Soal selidik	☐ Kajian intervensi Personal records Rekod peribadi
☐ Action research Kajian tindakan	☐ Secondary data analysis Analisis data sekunder
Observation Pemerhatian	Others (provide details): Lain-lain (nyatakan):
☐ √	☐
☐ T	☐

Part B2
Bahagian B2

1. Background:
Latar belakang:

A brief explanation of the problem to be studied and literature review (citations) to support.
Keterangan ringkas tentang masalah yang dikaji dan soroton kajian (sitasi) untuk menyokong keterangan tentang masalah yang dikaji.

There is an urgent need to address escalating prevalence of Type 2 Diabetes Mellitus (T2DM) and obesity in Malaysia. This estimates approximately 5 million (5,019,359) adult individuals in Malaysia with probable prediabetes in 2019 and future risk of diabetes. Prediabetes is an important risk factor for future diabetes and cardiovascular disease (CVD). It is a potentially reversible condition with lifestyle modification.

In Malaysia, a nationwide survey conducted in 2019 revealed a rising trend in obesity prevalence, increasing from 15.1% in 2011, to 17.7% in 2015, and finally to 19.9% in 2019. There is strong evidence that combination of diet plus physical activity reduces or delays the incidence of T2DM in prediabetes, particularly in IGT patients.

Very Low Carbohydrate Diet (VLCBD) (defined as daily consumption of carbohydrate of less than 50g) may be an easy, practical and adaptable lifestyle modification that has been proven to be effective in improving glycemic control and reducing inflammation in patients with T2DM. However, there is limited data to demonstrate a substantial effect on patients with prediabetes.

This study will provide further understanding on the effect of VLCBD in this group of patients, including the feasibility and safety of the diet among the diverse ethnic groups in Malaysia. It aims to explore the effects on insulin resistance, cardiovascular risk markers, anthropometric measurements and whole-body fat measurement with a body impedance analysis.

It is believed that adapting to a low carbohydrate diet can be a real challenge because of several reasons which include a lack of awareness that diabetes is a dietary disease, or the availability of alternative diet/food options or substitutes as well as the cost that accompanies it (but not necessarily so). Reducing carbohydrate intake may be compensated by an increased proportion of other macronutrients like protein and fat intake. In western population this usually easily replaced with dairy based product, beans, legumes, salads, and animal proteins. There are challenges but these can be minimized or overcome through educating and motivating the patients.

Subjects would be randomized into very low carbohydrate-based diet and standard balanced diet in a 1:1 ratio. The study duration would be for 12 weeks. All subjects would be provided a maximum of 25-30 kcal/kg/day per day with standard exercise and lifestyle changes advice. All the patients will have a consultation with healthcare professional. This initiative is in line with the SDG Goal 3.4 which is to reduce non-communicable diseases, including overweight and obesity, by 2030. This will subsequently lead to reductions in mortality from these conditions.

Problem statement (Less than 100 words)**:**
Penyataan masalah (Kurang dari 100 patah perkataan):

There is an urgent need to address the worsening prevalence of prediabetes and obesity in the country. Nutrition therapy or the understanding in the role of food restrictions as part of standard therapy is increasingly important. The efficacy of very low carbohydrate-based diet (VLCDB) in patients with prediabetes is currently unknown. Its effects on glycaemic control, insulin resistance level and other anthropometric parameters in this population are also limited and need to be explored.

References:
Rujukan:

Only include references cited in this document. Do not paste all your references from your main proposal.
Hanya sertakan rujukan yang dipetik dalam dokumen ini. Jangan tampalkan semua rujukan dari kertas cadangan utama anda

1. Leslie, W.S., Ford, I., Sattar, N. et al. The Diabetes Remission Clinical Trial (DiRECT): protocol for a cluster randomised trial. BMC Fam Pract 17, 20 (2016). https://doi.org/10.1186/s12875-016-0406-2
2. Ebbeling CB, Feldman HA, Klein GL, Wong JMW, Bielak L, Steltz SK, Luoto PK, Wolfe RR, Wong WW, Ludwig DS. Effects of a low carbohydrate diet on energy expenditure during weight loss maintenance: randomized trial. BMJ. 2018 Nov 14;363:k4583.
3. Griauzde DH, Hershey C, et al. Testing a very low-carbohydrate adaption of the Diabetes Prevention Program among adults with prediabetes: study protocol for the Lifestyle Education about prediabetes (LEAP) trial, September 2022. https://pubmed.ncbi.nlm.nih.gov/36176003/
4. Dorans KS, Bazzano LA, Qi L, He H, Appel LJ, Samet JM, Chen J, Mills KT, Nguyen BT, O'Brien MJ, Uwaifo GI, He J. Low-carbohydrate dietary pattern on glycemic outcomes trial (ADEPT) among individuals with elevated hemoglobin A1c: study protocol for a randomized controlled trial. Trials. 2021 Feb 1;22(1):108. doi: 10.1186/s13063-020-05001-x. PMID: 33522954; PMCID: PMC7848246.
5. Sepah SC, Jiang L, Ellis RJ, McDermott K, Peters AL. Engagement and outcomes in a digital Diabetes Prevention Program: 3-year update. BMJ Open Diabetes Res Care. 2017 Sep 7;5(1):e000422. doi: 10.1136/bmjdrc-2017-000422. PMID: 28948027; PMCID: PMC5595194.
6. Kimura M, et al. A Randomized Controlled Trial of a Mini Low-Carbohydrate Diet and an Energy-Controlled Diet Among Japanese Patients With Type 2 Diabetes.

2. Research objectives:
Objektif penyelidikan:

Number your objectives
Nomborkan objektif anda

1. To determine the effects of VLCBD in comparison to standard diet on weight loss and insulin resistance among patients with prediabetes and obesity.
2. To determine the effects of VLCBD in comparison to standard diet on muscle mass and whole body fat measurements with Body Impedance Analysis (BIA) in patients with prediabetes and obesity
3. To determine the feasibility and safety of VLCBD among patients with prediabetes and obesity.
4. To determine changes in hsCRP and Apo(A) following 12 weeks of VLCBD.

3.	**Expected benefits** (Less than 100 words)**:** Faedah yang dijangka (Kurang dari 100 patah perkataan): • This study aims to enhance understanding of the effects of a Very Low Carbohydrate Diet (VLCBD) in individuals with prediabetes and metabolic syndrome in Malaysia. It will provide evidence on VLCBD's impact insulin resistance, cardiovascular risk markers, and body composition which result in diabetes and obesity prevention. • The findings will support reduction in non-communicable diseases, and could lead to better healthcare outcomes, improved quality of life for participants, and a reduction in healthcare costs related to T2DM and obesity.
4.	**Date of research commencement-end:** Tarikh penyelidikan bermula-berakhir: This study will be conducted from April 2024 until Sept 2025.
5.	**Expected date of initial data collection:** Jangkaan tarikh pengumpulan data bermula: At least TWO (2) months after submission of this form Sekurang-kurangnya DUA (2) bulan selepas penghantaran borang ini April 2024
6.	**Location of research (please list all):** Lokasi penyelidikan dijalankan (senaraikan semua): Endocrine Clinic UiTM Sg Buloh and Hospital Al-Sultan Abdullah (HASA), Universiti Teknologi MARA (UiTM)
7.	**Research design dan methodology:** Rekabentuk penyelidikan dan metodologi: This is an investigator-initiated, single center, randomized, controlled, clinical trial in patients with prediabetes, comparing 12-weeks of VLCBD to standard diet therapy. Patient selection and recruitment would be conducted at the Endocrinology clinic of UiTM (Sungai Buloh and Puncak Alam). who meet the inclusion and exclusion criteria will be invited to participate in

the study.

Patient recruitment process will be carried out in clinic. Suitable candidate will be screen, given information sheet and invited to join the study. Patient can bring the information sheet home if they need more time to digest the information. Patient can call back if they agree to participate to sign the informed consent form in the clinic.

Individual characteristics:

1) Age (Years)
2) Gender (Male/ Female)
3) Race (Malay/ Chinese / Indian / Others)
4) Comorbidities (IHD / Hypertension/ Dyslipidemia/ Fatty liver)

The parameters to be studied during the visit will be measured by the same staff, including:

1) Weight in kilogram, measured without shoes using the same calibrated balance beam scale .
2) Height in meter, measured without shoes using the same stadiometer.
3) Body mass index (BMI); weight divided by height squared in meter (kg/m2) will be calculated.
4) Waist Circumference in centimeter using non elastic tape placed between midpoint of two iliac crest and lowest rib. [14]
5) Hip Circumference in centimeter using the same non elastic tape, measured at the largest circumference around the buttocks.
6) Waist to hip ratio calculated by dividing the waist circumference (WC) by the hip circumference (HC)

Very low carbohydrate diet

Patients within the VLCBD group will be given a prescription diet of less than 50g of carbohydrate daily. This diet adjustment will be guided by team members in the clinic, and supplemented by visual aids on carbohydrate counts of various local food. This study is focused on low carbohydrate intake while providing adequate calorie requirements from increased intakes of protein and healthy fats.

Patients would be given the options to choose their most appropriate food types which will amount to the carbohydrate count given. The macronutrient substitution to carbohydrate in the form of proteins and healthy fats would be recommended to participants based on patients' preferences and the minimum daily requirements of 0.8g-1.2g/kg/day for protein and 33g of fat.

Standard caloric intake and nutritional counselling

The same level of daily caloric intake should be advised for both dietary groups. Patients received dietary consultation by team members : pre-intervention and every visit of the study period. Each session lasted approximately 15 min.

For both groups, patients will be provided guidance regarding the restriction of daily energy intake to 25 - 30 kcal/kg of their ideal body weight after determining the patients' ideal body weight (height (m)2 × 22).

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Standard exercise

Intensive behavioural lifestyle intervention program modelled on the Diabetes Prevention Program (DPP) should be advocated for all prediabetic patients to achieve moderate-intensity physical activity (such as brisk walking) for at least 150 min/week.

Blood Investigations will be arranged:

Blood test needs to be done in the morning (9-10am) after overnight fasting of at least 8 hour to get more accurate fasting blood glucose, Renal profile , Fasting serum lipid , insulin , hsCRP , APO(a) , HbA1c . Subject also will be asked to start recoding the SMBG which will be taken as baseline glucose reading. Later subjects would undergo bloc randomization via a computer software program to either a VLCBD or standard diabetic diet group in 1:1 ratio. Both groups will be given standard therapy including advice on dietary and physical activity.

HOMA-IR

The homeostasis model assessment-estimated insulin resistance (HOMA-IR) has been widely used for the estimation of insulin resistance in research. It is calculated multiplying fasting plasma insulin (FPI) by fasting plasma glucose (FPG), then dividing by the constant 22.5, i.e. HOMA-IR=(FPI×FPG)/22.5.

The use of HOMA-IR for the evaluation of insulin sensitivity (but not beta cell function) has also been validated in patients with type 2 diabetes treated with insulin under certain condition (1).

In this study, HOMA-IR measurement will follow a standard protocol with additional instruction in relation to insulin use as per previous study (1). Serum insulin and glucose level will be measured in the morning during fasting

Body Fat Analysis :

All patients will undergo the InBody 380 Body Fat Analyzer test, performed by myself, to measure body fat mass (in kg) and percentage on the same day as their clinic visit. They must remove stockings and any metal items before the test. Patients should stand upright on the platform with their arms extended down and away from the torso, and their legs spread apart to avoid short circuits, faster current flow, and underestimation of body fat percentage. Body fat mass in kg and percentage will be recorded, and fat mass index will be calculated by dividing body fat mass (kg) by height (m^2).

Study Visits

Patients in VLCBD group are also scheduled to attend additional visit weekly in the first 4 week and every 2 weeks thereafter to supervise adherence, appropriate diet adjustment, and safe medication titration. Data including blood test, anthropometry and diet history would be obtained at week 0 and week 12 for all patients. The visits will be conducted at the Endocrine Clinic, however virtual meeting is also provided for those who are unable to attend physically. All patients will be required to fill in a food diary and exercise.

8.	**Ethical considerations related to the research** (e.g., consent, confidentiality, data storage, data security, or any related ethical considerations for your research): Pertimbangan etika yang berkaitan dengan penyelidikan (cth., persetujuan, kerahsiaan, penyimpanan data, keselamatan data atau sebarang pertimbangan etika yang berkaitan untuk penyelidikan anda): Ethical approval will be obtained from the University Research Ethics Committee of Universiti Teknologi MARA (UiTM). Permission to collect data at the Endocrine clinic of Hospital Al-Sultan Abdullah (HASA), Universiti Teknologi MARA (UiTM) Puncak Alam will be obtained. Patient information will be kept confidential by the investigators and will not be made public unless disclosure is required by law. Patient may refuse to take part in the study or may withdraw themself from participation in the research at any time without penalty.

9. **Inclusion and exclusion criteria:**
Kriteria kemasukan dan pengecualian:

Inclusion criteria:
Kriteria kemasukan:
Characteristics of your participants (Ciri-ciri peserta kajian anda)

- Age between 30-65 years
- BMI 23-40 kg/m2
- Diagnosed with pre diabetes (either FBS 5.6 mmol–6.9 mmol/L or HbA1c 5.6-6.2%)
- Able to stand and non-amputee
- Able to provide informed consent

Exclusion criteria:
Kriteria pengecualian:
Characteristics that disqualify prospective participants from joining this study (Ciri- ciri yang membatalkan calon peserta untuk mengikuti kajian ini)

- Type 1 or Type 2 DM
- Calculated Creatinine Clearance of < 60 mls/min/1.73 m2
- Heart failure (New York Heart Association functional class III–IV), active systemic inflammatory disease, chronic renal failure requiring hemodialysis, active hepatic disease and collagen disease
- Malignancy
- Acute coronary syndrome within the 3 months preceding admission
- Pregnant women, breastfeeding or planning to conceive within the next year

10. **Sample size:**
Saiz sampel:
State the sampling method and minimum sample size
Nyatakan kaedah persampelan dan saiz sampel minima

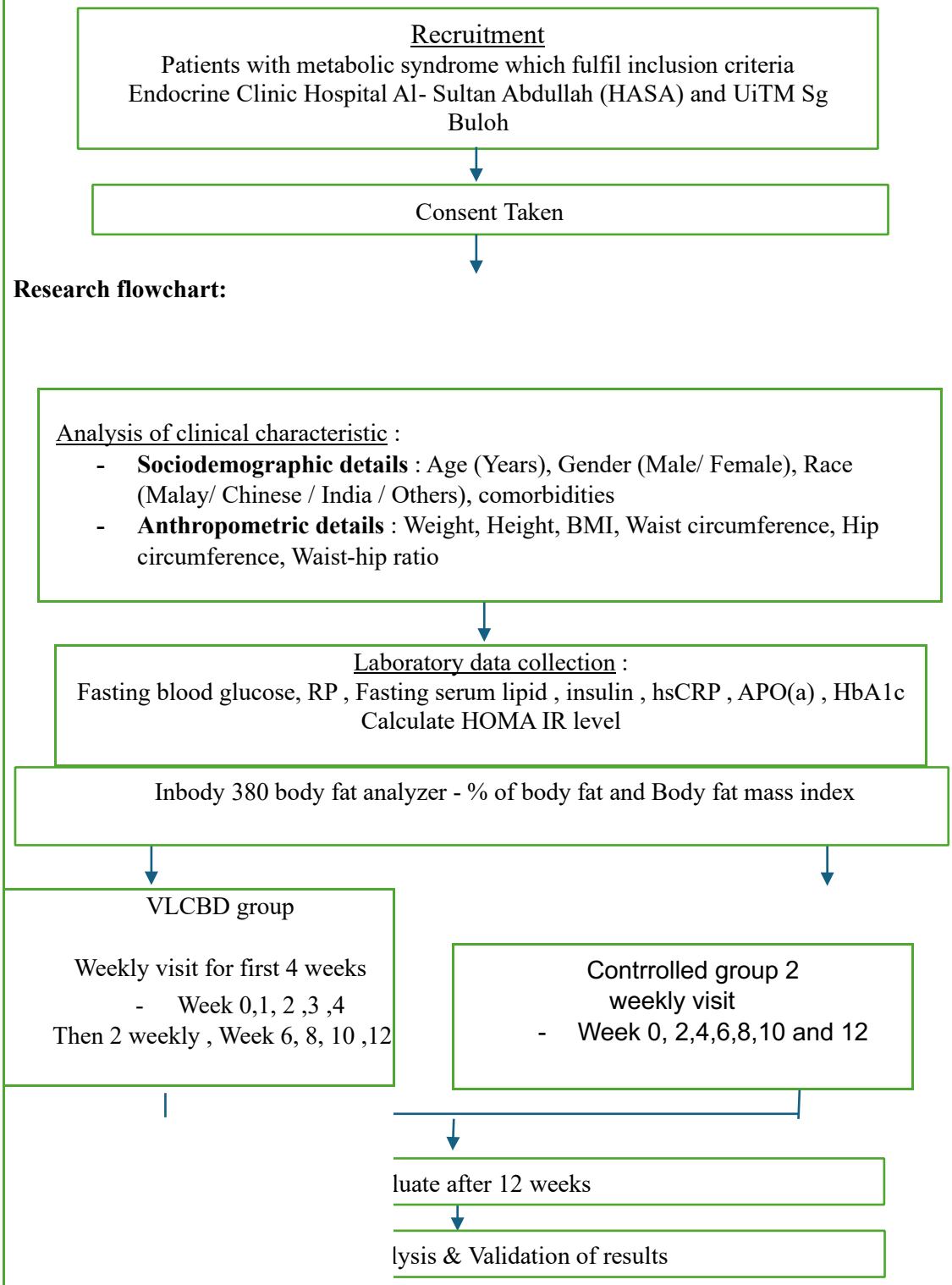
The sample size was calculated using the formula for comparison of two independent means, based on the primary outcome of change in anthropometric parameters. The calculation was informed by a previous 12-week randomised controlled trial of a very-low-carbohydrate diet conducted by Zainordin et al [18]. Assuming a two-sided significance of 0.05 and a statistical power of 80%, the minimum required sample size was 9 participants per group (18 participants in total). After allowing for an anticipated 50% attrition rate, the required sample size was 18 participants per group, giving a total sample size of 36 participants for this study.

Pengiraan:
Calculation:
State the formula and reference(s) used to determine the minimum sample size
Nyatakan formula dan rujukan yang digunakan untuk menentukan saiz sampel minima

The minimum sample size was calculated using the formula for comparison of two independent means: $n = 2\sigma^2(Z_{1-}\alpha/2 + Z_{1-}\beta)^2 / d^2$

11.

Carta alir penyelidikan:



12. **Statistical analysis:**

Analisa statistik:

Briefly describe the data analysis and statistical sotfware that will be utilized

Huraikan secara ringkas analisis data dan perisian statistik yang akan digunakan

Statistical analysis will be conducted using the SPSS 24.0 software (SPSS, Inc. Chicago, IL,

USA). The expected outcomes to be measured Fasting blood glucose, RP , Fasting serum lipid , insulin , hsCRP , APO(a) , HbA1c and boy fat analysis are compared between intervention and control group.

Values are expressed as mean ± standard error (SE) for baseline characteristics, or median (interquartile range) for the results of the statistical analyses and absolute values for the remaining parameters. The effects of expected outcomes were evaluated using a paired *t*-test.

The criterion for therapy completion in the study was defined as the availability of follow-up data from the baseline up to week 12 of the study. Incomplete follow-up data (weeks 4, 8 and 12) were imputed using the "last observation carried forward" method.

13. Gantt chart:

Carta Gantt:

	GANTT CHART	Year 1												Year 2											
		2024												2025											
		Jan	*Feb*	*Mar*	*Apr*	*May*	*Jun*	*Jul*	*Aug*	*Sept*	*Oct*	*Nov*	*Dis*	*Jan*	*Feb*	*Mar*	*Apr*	*May*	*Jun*	*Jul*	*Aug*	*Sept*	*Oct*	*Nov*	*Dec*
1	Literature Review																								
2	Budget Review																								
3	Thesis proposal																								
4	Patient Recruitment by phases																								
5	Patient Follow-Up for 12 weeks consultation																								
6	Procurement of reagents and sample testing																								
7	Data Collection And Analysis																								

1.	**Grant / Source:** Geran / Sumber:	DUCS grant

2.	**Date of grant approval:** Tarikh kelulusan geran:	1 October 2022

* If not applicable please write '-NA-' in the spaces provided.
Jika tiada kaitan sila tulis '-NA-' di ruangan disediakan.

Part C: Funding details

Bahagian C: Maklumat Dana

3.	**Total allocation:** Jumlah peruntukan:	RM62,500
4.	**Duration of grant:** Jangkamasa peruntukan:	2 years with 6 months extension
5.	**Others:** Lain-lain:	NA

Items	Price per unit	Quantity	Price
Consent paper (Malay/English)	RM 0.40	50	RM20.00
Diary and brochure	RM 1.00	50	RM50.00
Blood taking	Insulin RM40.00 Fasting plasma RM9.00 Renal profile RM21.50 Pathology overhead charge RM4.00 HsCRP RM 69.50 APO (a) RM57.90		RM10, 095
Body fat analysis	RM20.00	50	RM1000.00
Patient's visit	RM50.00 / visit	50 - Intervention (9 visits) - Controlled group (7 visits)	RM 40,000
Total			RM 51,195.00

Part D: Agreement to conduct the research project.

Bahagian D: Pengesahan persetujuan menjalankan penyelidikan.

Must be completed and signed by all members of the research group.
Mesti dilengkapkan dan ditandatangani oleh semua ahli kumpulan penyelidikan.

1. Applicant (to be filled by Undergraduate/Masters by Coursework Student only) Pemohon (untuk dilengkapkan oleh Pelajar Siswazah / Sarjana Kerja Kursus sahaja)

Name: Nama:	NUR ADILA BINTI MUHAMMAD ZAWAWI	
Staff ID/Student ID: No. Staf/No. Pelajar:	2023459656	
Position/ Specialisation: Jawatan/ Kepakaran:	MEDICAL OFFICER	
Affiliation: Jabatan:	INTERNAL MEDICINE	
Office: Telefon pejabat:		
Mobile phone: Telefon bimbit:	0126522611	
Email: Emel:	nuradilazawawi@gmail.com	
Signature: Tandatangan:		**Date:** Tarikh: 16th February 2025

2. Main Supervisor Penyelia Utama

Name: Nama:	DR NUR AISYAH ZAINORDIN	
Staff ID/Student ID: No. Staf/No. Pelajar:	300904	
Position/ Specialisation: Jawatan/ Kepakaran:	INTERNAL MEDICINE SPECIALIST/ENDOCRINOLOGIST	
Affiliation: Jabatan:	INTERNAL MEDICINE	
Office: Telefon pejabat:		
Mobile phone: Telefon bimbit:	0192597751	
Email: Emel:	nuraisyah0904@uitm.edu.my	
Signature: Tandatangan:		**Date:** Tarikh: 16th February 2025

3. Penyelidik Bersama / Penyelia Bersama Co-Researcher / Co-Supervisor

Name: Nama:	PROF . DR ROHANA ABD GHANI	
Staff ID/Student ID: No. Staf/No. Pelajar:	311773	
Position/ Specialisation: Jawatan/ Kepakaran:	Consultant Endocrinologist	
Affiliation: Jabatan:	Internal Medicine	
Office: Telefon pejabat:		
Mobile phone: Telefon bimbit:	0125177326	
Email: Emel:	rohana1773@uitm.edu.my	
Signature: Tandatangan:		**Date:** Tarikh: 16th February 2025

Name: Nama:	PROF. DR CHEN XIN WEE
Staff ID/Student ID: No. Staf/No. Pelajar:	320612
Position/ Specialisation: Jawatan/ Kepakaran:	Public health medicine specialist
Affiliation: Jabatan:	Public health medicine
Office: Telefon pejabat:	
Mobile phone: Telefon bimbit:	0122839618
Email: Emel:	drchenxw@uitm.edu.my

Signature: Tandatangan:		**Date:** Tarikh: 16th February 2025

Part E: Research Risk Classification

Bahagian E: Klasifikasi Risiko Kajian

PLEASE ANSWER ALL QUESTIONS BELOW.

If your answer is '**Yes**' to any of the following questions, please include a brief information in the space provided.

SILA JAWAB KESEMUA SOALAN DI BAWAH.

Sekiranya jawapan anda **'Ya'** kepada mana-mana soalan di bawah, sertakan maklumat ringkas di ruang yang disediakan.

	PARTICIPANT PROFILE	No	Yes	Brief description (If YES)
1.	Are the participants children (under 18 years old)? Adakah peserta kanak-kanak (Umur di bawah 18 tahun)?	√		
2.	Are the participants from a particular vulnerable group? (e.g., mental disorder, mentally challenged, disabled, minority, disadvantaged group etc.) Adakah peserta daripada golongan rentan? (cth: kecelaruan mental, kelainan keupayaan intelektual, berkeperluan khas, minoriti dan sebagainya.)	√		
3.	Are any of these participants/patients in terminal care? Adakah peserta/pesakit ini memerlukan rawatan terminal?	√		
4.	Are any of these participants unable or are incapable of giving consent? (i.e., consent will be obtained indirectly from a legal guardian etc.) Adakah peserta tidak boleh atau tidak berupaya memberi izin? (spt: izin akan diambil secara tidak	√		

	langsung daripada penjaga sah dan sebagainya.)			
5.	Are the participants given any form of emolument to participate? Adakah peserta diberi sebarang emolumen untuk menyertai kajian?	√		
	PRIVACY AND CONFIDENTIALITY	No	Yes	Brief description (If YES)
6.	Does any of the data collected have the potential to cause discomfort, embarrassment, or psychological harm to the participants? (E.g. sexual orientation etc.) Adakah data yang dikumpul berpotensi untuk menyebabkan ketidak selesaan, keaiban atau gangguan psikologi kepada peserta? (cth: orientasi seksual dan sebagainya.)	√		
7.	Does your research involve measures undeclared to the participants? (E.g. covert observations etc.) Adakah penyelidikan anda melibatkan langkah-langkah yang tidak dimaklumkan kepada peserta? (cth: pemerhatian rahsia dan sebagainya.)	√		
8.	Will the collected data be made available to other parties not involved in the research? (e.g., government agencies) Adakah data yang dikumpulkan akan didedahkan kepada pihak lain yang tidak terlibat dalam penyelidikan? (cth. agensi kerajaan)	√		
	RISK OF HARM	No	Yes	Brief description (If YES)
9.	Will you be collecting biological samples e.g., body fluids? Adakah anda akan mengumpul sampel biologi contohnya: cecair badan?		√	Venous blood sample of amount 10mls of blood for Fasting blood glucose, RP , Fasting serum lipid , insulin , hsCRP , APO(a) , HbA1c
10.	Do you have access to any information that will allow the identification of individual human participants? Adakah anda mempunyai akses kepada apa-apa maklumat yang akan membolehkan pengenalpastian peserta secara individu?	√		
11.	Is the collection method invasive and has the potential to cause harm, pain or discomfort? (except finger, heel, ear prick.) Adakah kaedah pengumpulan invasif dan berpotensi menyebabkan kemudaratan, kesakitan atau ketidakselesaan? (kecuali tusukan jari, tumit, telinga.)		√	Causing minimal pain and discomfort over the blood taking site

12.	Will the participants be subjected to vigorous physical tests or exercise regime? (if 'No', go to Question 15.)	√		

	Adakah peserta akan melalui ujian fizikal atau senaman berintensiti tinggi? (jika 'Tidak', teruskan ke Soalan 15.)	√		
13	Are the participants non-athletes or patients with chronic illness? Adakah peserta bukan atlet atau pesakit dengan penyakit kronik?		√	Patient with chronic disease who are not in exclusion criteria can participate.
14	Will they be subjected to maximal exercise intensity? Adakah mereka akan melalui senaman berintensiti maksimum?	√		
15	Is there any form of procedure/ medication involved? Adakah terdapat sebarang prosedur/ ubat yang terlibat?	√		
16	Is there any drug or device used with an unapproved indication? Adakah terdapat ubat atau peranti yang digunakan dengan tanpa indikasi yang diluluskan?	√		
17	Can the informed consent be obtained from anyone other than the patient/participants? Adakah keizinan kajian telah didapati daripada sesiapa selain pesakit/peserta?	√		
18	Is there any kind of risk to the participants if he/she chose to withdraw? Adakah terdapat sebarang kemudaratan kepada peserta jika dia memilih untuk menarik diri?	√		
19	Will the samples obtained be stored for future research? Adakah sampel yang dikumpul akan disimpan untuk penyelidikan di masa hadapan?	√		
20	Do you propose to analyse the sample outside of the original purpose for which it was collected? Adakah anda bercadang untuk menganalisa sampel selain tujuan asal ia dikumpulkan?	√		
21	If 'Yes' to No. 20, have you obtained consent from participants for this purpose? Jika 'Ya' pada No. 20, adakah anda mendapat persetujuan daripada peserta untuk tujuan ini?			

22.	What type of biological samples collected? (Please indicate amount and frequency.) Apakah jenis sampel biologi yang dikumpul? (Sila nyatakan jumlah dan kekerapan.)		√	Venous blood sample of amount 10mls of blood Fasting blood glucose, RP , Fasting serum lipid , insulin , hsCRP , APO(a) , HbA1c
	OTHER ETHICAL ISSUES	No	Yes	Brief description (If YES)

23.	Are there any other ethical issues not stated in this checklist? Adakah terdapat sebarang isu etika lain yang tidak dinyatakan dalam senarai semak ini?	√		

Part F: Applicant Checklist

Bahagian F: Senarai Semak Pemohon

Terms of Submission of Ethics Approval Application			
1. Please ensure that all research team members have signed the application. 2. Please ensure that the application has been signed and endorsed by the Department or Postgraduate Research Sub-Committee. 3. All required documents must be submitted within two (2) months before the data collection. 4. Submission of all forms prescribed by the REC must be in English, with exception to research conducted in other languages (with Senate approval). 5. Any data collection instruments that require completion by respondents/participants must be prepared in the Malay and English languages, and other language(s) understood by the participants.			
	ITEM PERKARA	**YES** YA	**NO** TIDAK
1	Have you presented your proposal to the Department or Postgraduate Research Sub-Committee? Adakah anda telah membentangkan proposal anda di Jawatankuasa Kecil Penyelidikan Jabatan atau Pascasiswazah?	√	
2	Have you completed the C/F/B/CoE ERC1 form? Adakah anda telah melengkapkan Borang C/F/B/CoE ERC1?	√	
3	Have you completed the C/F/B/CoE ERC2 or and C/F/B/CoE ERC3 form? Adakah anda telah melengkapkan Borang C/F/B/CoE ERC2 atau dan borang C/F/B/CoE ERC3?	√	
4	Has your supervisor checked your application forms? Adakah penyelia anda telah menyemak borang permohonan anda?	√	
5	Has the form been signed by all researchers? Adakah borang ditandatangani oleh semua penyelidik?	√	

Additional comments (if any): Komen Tambahan (Jika Ada):	
Applicant's Signature	Date
Main Supervisor's Signature	Date

Part G: Verification from Department or Postgraduate Sub-Committee

Bahagian G: Pengesahan Jawatankuasa Kecil Jabatan atau Pascasiswazah

We have deliberated on the application and propose as below:

Kami telah meneliti permohonan ini dan mencadangkan seperti di bawah:

☐ Minimal risk research. Recommend for approval without presentation.
Penyelidikan melibatkan risiko minima. Dicadangkan untuk mendapat kelulusan tanpa pembentangan.

☐ More than minimal risk research. Recommend to forward to UiTM REC.
Penyelidikan melibatkan risiko melebihi minima. Dicadangkan untuk dihantar kepada UiTM REC.

Comment if any:
Ulasan jika ada:

Signature Tandatangan: **Coordinator / Head of Program** Koordinator / Ketua Pusat Pengajian	**Official stamp:** Cop rasmi:	**Date:** Tarikh: