#### Annexure I

#### **CONSENT FORM**

# Impact evaluation of pumpkin seeds on glycaemic and lipemic responses of type 2 diabetic old age population of urban Vadodara.

I \_\_\_\_\_\_ have been fully informed about the purpose of the study titled "Impact evaluation of pumpkin seeds on glycaemic and lipemic responses of type 2 diabetic old age population of urban Vadodara."

I have understood the implications of the study and I am willing to participate in the study.

Following biochemical estimations will be done under this study:

1. blood hemoglobin	2. fasting blood glucose	3. glycated haemoglobin
4. liver function test	5. kidney function test	6. lipid profile

Protocol for the study

- 1. Blood will be drawn once in fasting state.
- 2. The blood will be drawn by experienced lab technician.
- 3. Disposable syringes and needles will be used.
- 4. A copy of report will be provided for record.

The information that is collected will be kept confidential and no personal information will be revealed to anyone. No remuneration will be provided to the participants for being part of the study.

# Signature of investigator

Signature of participant

Name:

**Contact No:** 

#### PARTICIPANT INFORMATION SHEET

#### **CONSENT FORM**

# Impact evaluation of pumpkin seeds on glycaemic and lipemic responses of type 2 diabetic old age population of urban Vadodara

#### Study title

Impact evaluation of pumpkin seeds on glycaemic and lipemic responses of type 2 diabetic old age population of urban Vadodara is a randomized control trial to be carried out on the confirmed diabetic patients of urban Vadodara above age of 60 years.

PhD Guide	PhD Student
Prof.Komal Chauhan	Ms.Nikita Joshi
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#### Purpose of the study

Diabetes mellitus is one the major non-communicable diseases. It is the most prevalent metabolic condition and one of the major health problems worldwide. Diabetes mellitus is a growing problem worldwide because of long life expectancy and life style modifications. Diabetes mellitus complications and comorbidities are more frequent in elders compare to young group. One of the pharmacological ways to control blood sugar level is use of botanical products or functional foods. Among many functional foods, pumpkin seed is also one of the functional foods which is having many health benefits. Therefore, the purpose of the study is to supplement 10 gm or 15gm of pumpkin seeds for the period of 90 days to confirmed old age diabetic subjects of urban Vadodara.

### **Benefits and risk**

The present study will show to what extent glycaemic and lipemic responses can be improved after 45 days the supplementation of pumpkin seeds. After the 90 days, you will also get to know about the improvements in biochemical improvements, mental health and other parameters.

There is no risk involved in as the drawing of blood will be done by trained technician and estimations will be done at accredited lab. There are no side effects of daily consumption of minimum 10gm of pumpkin seeds as per scientific literature.

#### **Protocol of the study**

1. You will be asked to provide information regarding medical history, personal baseline information, details of your dietary and physical activity pattern with the help of questionnaire.

2. Your body measurements will be taken to assess the nutritional status.

3. You will be provided a sachets of 10gm or 15gm of pumpkin seeds, that you have to consume on a daily basis in a raw form.

4. 10ml blood in fasting state will be taken twice before and after the supplementation period to know the improvements in the biochemical parameters.

#### Cost

There is no financial burden to the participants for participation in the study. Participants will not be paid any remuneration for being in this study and will be a part on their willingness.

#### Confidentiality

Your identity in this study will be treated as confidential. Your personal information will not be shared to anyone but your results of the laboratory data will may be published for the scientific purpose. If any serious health condition will be detected during study, you will be informed about it and information will be given to doctor or clinic if require.

#### **Voluntary Consent**

Your decision to join in this study is voluntary. You may quit at any time for any reason without notice. If you have any questions about any part of the study, you have right to ask PhD student or guide to collect information before you sign this consent form.

#### **Participant's Statement**

I have clarified that I have read, or had read to me and I understand the description of the study. I voluntarily consent to join in this study.

Signature\_\_\_\_\_

Name\_\_\_\_\_

Date\_\_\_\_\_

\*\*\*

# સંમતિ પત્રક

અભ્યાસનું શિર્ષક : વડોદરા વિસ્તારના મોટી ઉંમરના મધુપ્રમેહથી પીડાતા વ્યક્તિઓ ઉપર કોળાના બીજની અસરનું મુલ્યાંકન.

મે. ..... માહિતી વાંચી છે તથા મને ઉપર્યુક્ત અભ્યાસનો હેતુ સમજાવવામાં આપેલી માહિતી વાંચી છે તથા મને ઉપર્યુક્ત અભ્યાસનો હેતુ સમજાવવામાં આવેલ છે.

મને આ અભ્યાસનું સ્વરૂપ સમજાવવામાં આવ્યું છે અને આ અભ્યાસમાં મને સામેલ કરવા માટે હું મારી સંમતિ આપુ છું.

આ અભ્યાસના ભાગરૂપે નીચે જણાવેલ પેરામિટરની તપાસ કરવામાં આવશે.

- ૧. હિમોગ્લોબીનની તપાસ
- ૨. ફાસ્ટિંગ બ્લડ ગ્લુકોસ (ભુખ્યા પેટે)
- 3. પોસ્ટ પ્રેન્ડિચલ બ્લડ શુગર (જમ્ચા ના ૨ કલાક પછી)
- ૪. લીવર ફંક્શન ટેસ્ટ
- ૫. કીડની ફંક્શન ટેસ્ટ
- ૬. લીપીડ પ્રોફાઇલ.

અભ્યાસનું સ્વરૂપ :

- ૧. ભુખ્યાપેટે લોહીની એક વખત તપાસ કરવામાં આવશે.
- ૨. લોઠીની તપાસ અનુભવી ટેક્નીશીચન દ્વારા કરવામાં આવશે.
- ૩. ડિસ્પોઝેબલ સોચ વાપરવામાં આવશે.
- ૪. તમારી જાણ માટે તમને રિપોર્ટની કોપી આપવામાં આવશે.

તમારી માહિતી અને રીપોર્ટ ખાનગી રાખવામાં આવશે. અભ્યાસમાં ભાગ લીધા બદ્દલ કોઈપણ પ્રકારનું નાણાકીચ વળતર આપવામાં આવશે નહી.

સંશોધકનાં હસ્તાક્ષર

ભાગ લેનારના હસ્તાક્ષર

ભાગલેનારનું નામ : ફોન નં. :

# શોધકર્તાનું પ્રમાણપત્ર સંમતિ પત્રક

અભ્યાસનું શિર્ષક : વડોદરા વિસ્તારના મોટી ઉંમરના મધુપ્રમેહથી પીડાતા વ્યક્તિઓ ઉપર કોળાના બીજની અસરનું મુલ્યાંકન.

પી.એચ.ડી. ગાઇડ પ્રો. કોમલ ચૌઠાણ ડીપાર્ટમેન્ટ ઓફ કુડ એન્ડ ન્યુટ્રીશીયન ફેકલ્ટી ઓફ ફેમિલી અને કમ્યુનિટી સાઇન્સઇસ (મો.) : ૯૮૯૮७ ૯૦૩૪૦

પી.એચ.ડી. સ્ટુડન્ટ નિકીતા જોશી (મો.) : ૮૫૧૧૨ ૨૦૮૬૯

અભ્યાસનો દેતુ :

ડાચબિટીસ ઝડપથી આગળ વધતો બિન–ચેપી રોગ છે. લાંબી આચુ – મર્ચાદા તથા બદલાતી જીવનશૈલી ના કારણે ડાચબિટીસની આડઅસરો ચુવાનો કરતા વડીલોમાં વધુ જોવા મળે છે. ઔષધિ વનસ્પતિ તથા ફંક્શનલ કુંડનો ઉપયોગ બ્લડશુગરને નિચંત્રિત રાખવા મદદરૂપ છે. કોળાના બીજમાં ઘણા બધા ફાચદાકારક ગુણધમો છે જે ડાચબિટીસને નિચંત્રણમાં રાખવા મદદરૂપ છે. તેથી આ સંશોધનનો મુખ્ય દેતું ૧૦ ગ્રામ કોળાના બીજની ૯૦ દિવસ સુધી વડોદરા શહેરના ડાચબિટીસથી પીડાતા વડીલોની સારવાર, કરવાનો છે. સમગ્ર વિશ્વમાં ડાચબિટીસ ઝડપથી ફેલાઇ રહ્યો છે.

ફાચદાઓ :

૯૦ દિવસ કોળાના બીજનું સેવન કરવાથી કેટલા હૃદ સુધી ગ્લાચસિનિક અને લાચપિમિક પ્રોફાઇલ સુધરી શકે છે તે આ સંશોધન દ્વારા પુરવાર થશે. ૯૦ દિવસ બાદ, તમારા રિપોર્ટ અને તબિચતમાં થચેલ સુધારા અંગે તમને માહિતી આપવામાં આવશે.

લોહીની તપાસ અનુભવી ટેક્નીશીચન દ્વારા કરવામાં આવશે તથા રિપોર્ટસ પણ NABL માન્ય લેબોરેટરીમાં કરવામાં આવતા હોવાથી કોઇપણ જાતનું જોખમ નથી. વૈજ્ઞાનિક પુરાવા મુજબ દરરોજ ૧૦–૧૫ ગ્રામ કોળાના બીજનું સેવન કરવાથી કોઇપણ જાતની આડઅસર થતી નથી. અભ્યાસનું સ્વરૂપ ઃ

- તમને તમારી મેડિકલ હિસ્ટ્રી, પ્રાથમિક માહિતી, રોજંદી આહાર તેમજ દીનચર્ચાની માહિતી પ્રશ્નોતરી દ્વારા આપવાની રહેશે.
- ર. તમારું પોષણ સ્તર જાણવા માટે શરીરના માપ લેવામાં આવશે.
- 3. તમને ૧૦–૧૫ ગ્રામના કોળાના બીજના પેકેટ આપવામાં આવશે જે તમને દરરોજ ખાવાના રહેશે.
- ૪. તમારા શરીરમાં કોળાના બીજના પરિણામને ચકાસવા ૧૦ મિલી જેવુ રક્ત ભુખ્યા પેટે બે વખત સંપુર્ણ અભ્યાસ દરમિયાન લેવામાં આવશે.

નાણાકીચ ખર્ચ / કિંમત :

સંપૂર્ણ અભ્યાસ દરમિયાન ભાગલેનાર વ્યક્તિ પાસેથી કોઈપણ પ્રકારના નાણાં લેવામાં આવશે નહી. ભાગ લેનાર વડીલોએ સ્વેચ્છાથી અભ્યાસમાં ભાગ લેવો, તે બદ્દલ તેમને કોઈપણ પ્રકારનું વળતર ચુકવવામાં આવશે નહી.

માહિતીની ગુપ્તતા :

તમારી ઓળખ ગુપ્ત રાખવામાં આવશે. તમારી માહિતી કોઇને પણ આપવામાં આવશે નહી, માત્ર પરિણામો નો ઉપયોગ પબ્લિકેશન કરવાના હેતુથી કરવામાં આવી શકે છે. સંપુર્ણ અભ્યાસ દરમિયાન જો કોઈ ગંભીર સ્થિતિ આવે તો તમને જરૂરિયાત મુજબ ડૉક્ટર પાસે મોકલવામાં આવશે.

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સ્વૈચ્છિક પ્રમાણ પત્ર :
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અભ્યાસમાં જોડાવા માટેનો તમારો નિર્ણય સ્વૈચ્છિક છે. તમે કોઇપણ સમયે અભ્યાસમાંથી નીકળી શકો છો. તમને અભ્યાસ અંગે કોઇપણ માહિતી પી.એચ.ડી. સ્ટુડન્ટ અથવા સંશોધક પાસેથી મેળવવાનો અધિકાર છે.

આ અભ્યાસ માટે જરૂરી પરવાનગી અથિકલ કમિટીના તજજ્ઞ પાસેથી લીધેલી છે.

ભાગલેનારનું પ્રમાણપત્ર :

હુ અહીં બાહેંધારી આપુ છું કે મે અભ્યાસ અંગેની તમામ વિગતો વાંચેલી છે અને આ સંશોધનમાં જોડાવાનો મારો નિર્ણય સ્વૈચ્છિક છે.

તારીખ ઃ

હસ્વાક્ષર

লাস :

#### **Annexure III**

# Impact evaluation of pumpkin seeds on glycaemic and lipemic responses of type 2 diabetic old age population of urban Vadodara.

#### **QUESTIONNAIRE FOR THE INFORMATION**

CODE NO:

#### A. BACKGROUND INFORMATION

1. Name:

- 2. Age:
- 3. Gender: Male/Female/Others
- 4. Address:
- 5. Contact Number;
- 6. Religion: Hindu/Muslim/Sikh/Jain/Christian/Others
- 7. Marital Status: Married/Unmarried/Divorced/Widow/Widower
- 8. Educational level: Primary/Secondary/Higher secondary/Graduate/Post-Graduate/Others
- 9. Occupation: Service/Business/Housewife/Retired/Other
- 10. Type of family: Nuclear/Joint/Extended
- 11. No. of family members:
- 12. Total family income (Monthly) :
- 13. Per capita income:

#### FAMILY HISTORY

Туре	Mother	Father	Sibling 1	Sibling 2	Sibling 3	Grand parents
Obesity						
Diabetes						
Hypertension						
CVD						
Hyperlipidaemia						
Stroke						
Thyroid						
Cancer						
Asthma						
Any						
other(Specify)						

#### **B. MEDICAL HISTORY**

1. How often do you go for medical health check-up? Once in a month/once in three months/once in a six month/once in a year/never

#### 2. Present medical problems

Serial no.	Medical problem	Since how long	Less than 5
1	Obesity		
2	Diabetes		
3	Hypertension		
4	Heart disease		
5	Hyperlipidaemia		
6	Stroke		
7	Thyroid		
8	Cancer		
9	Asthma		
	Kidney stones		
10	Osteoporosis		
10	Other (specify)		

#### C. INFORMATION REGARDING DIABETES MELLITUS

1. Duration of disease:

2. Cause of diabetes: Surgery/Infection/Genetic/Obesity/Pregnancy/Others

3. Present Symptoms: Polyuria (Excess urination)/ Polydipsia (Excess thirst)/ Polyphagia (Excess hunger)/ Neuropathy/ Fatigue/Unexpected weight loss/ Retinopathy (Blurred vision)/ slow healing of wounds/ Edema/Gangrene

4. Treatment Following : Diet modification/ Drugs/ Insulin/ Combination of diet and other/Physical activity/Homeopathic/Ayurvedic

#### **D. OTHER INFORMATION**

1. Are you taking any medicines presently? Yes/No

2. If yes, Name of medicine \_\_\_\_\_, Frequency \_\_\_\_\_, From when \_\_\_\_\_.

3. Are you taking any kind of nutritional/herbal supplement? Yes/No

4. If yes, Name of product \_\_\_\_\_\_.

#### LIFE STYLE INFORMATION

### E. habitual profile

Туре	Currently taking	Past habit
Tea coffee		
Tobacco		
Pan		
Padiki		
Gutka		
Smoking		
Alcohol		

#### **DIETARY HABITS**

1. What type of diet do you take? Vegetarian/Non-Vegetarian/ Ovo-Vegetarian

2. How many meals do you consume on regular basis? Breakfast/Brunch/Lunch/Evening snacks/Dinner/Bed time milk

3. What is your daily water intake? <6 glasses/6-8 glasses/>8 glasses

4. What type of cooking oil you preferred to use? \_\_\_\_\_

5. How much oil do you buy for every month?

6. Do you use same cooking oil for every year? Yes/No

7. How do you use oil which remains after deep frying?

a. Discard it

- b. Use it again for frying
- c. Use it in preparing vegetables
- 8. No. of cups of tea/coffee per day \_\_\_\_\_

9. Quantity of sugar purchased in a month \_\_\_\_\_(exclude sugar restricted person)

10. Quantity of salt purchased in a month \_\_\_\_\_

11. What type of food you avoid to control your diabetes? Rice/Potato/Sugar/Jaggery/biscuits/any other

12. How frequently you eat outside food? 2-3 times in a week/Once in a week/ Once in a fifteen days/Once in a month/Occasionally/Never

#### 13. Food Frequency checklist

Name of Food	Daily	weekly	Monthly	Never
Fruits				
Vegetables				
Green leafy				
vegetables				
Milk				
Curd				
Buttermilk				
Fried foods				
Biscuits				
Rusk				
Khari				
Soft drinks				
Ice-cream				
Namkeen				
Pure ghee				
Egg				
Fish				
Mutton				
Chicken				
Sugar free tea				
Without sugar tea				
Regular				
Shree khand				
Kheer				

Basundi		
Pedha		
Barfi		
Fruit custard		

#### Anthropometry measurements:

1. Weight (kg)\_\_\_\_\_

2. Height (Cm) \_\_\_\_\_

3. BMI \_\_\_\_\_

# **Bio-physical measurements**:

1. Blood pressure (mm of Hg)\_\_\_\_\_

2. Pulse rate \_\_\_\_\_

# Annexure IV CONSENT FORM FOR SENSORY EVALUATION

# STUDY TITLE: Impact evaluation of pumpkin seeds on glycaemic and lipemic responses of type 2 diabetic old age population of urban Vadodara.

#### PhD Guide

Prof.Komal Chauhan Department of Foods and Nutrition, Faculty of Family and Community Sciences, The M S University of Baroda, Vadodara (M): 9898790340

#### PhD Student

Ms.Nikita Joshi Department of Foods and Nutrition, Faculty of Family and Community sciences, The M S University of Baroda, Vadodara (M):8511220869

# Purpose of the study

Diabetes mellitus is one the major non-communicable diseases. It is the most prevalent metabolic condition and one of the major health problems worldwide. Diabetes mellitus is a growing problem worldwide because of long life expectancy and life style modifications. Diabetes mellitus complications and comorbidities are more frequent in elders compare to young group. One of the pharmacological ways to control blood sugar level is use of botanical products or functional foods. Pumpkin seeds have the potential to reduce glycaemic response. Decreasing the glycaemic index of the diet may improve insulin sensitivity, reducing the risk of diseases. This study has been planned to determine the glycemic index of pumpkin seed incorporated recipes.

# PROTOCOL OF THE STUDY

If you decide to join this study, information regarding medical history, family history of lifestyle diseases will be assessed with the help of questionnaire. There will be approximately four visits lasting approximately 130 minutes in each visit. On two of the study visits you will be asked to consume 50 gm of glucose as reference food. On other two visits, you will be asked to consume standard recipe (Without pumpkin seeds) or the test recipe (With pumpkin seeds). Both of them will contain 50gm of carbohydrates and will be tested on separate days. Each study visit will include following procedures:

- You should not drink or eat any food substance before 12 hours of the study visit.
- Avoid any vigorous exercise in the morning of a visit.
- Provide fasting blood sample taken by finger prick.
- Consume specified portion of reference or test food within 15 minutes.
- Provide finger prick blood sample at 15, 30,45,60,90 and 120 minutes after beginning to eat the food.

### Costs:

This study only requires your time and cooperation. All the cost will be borne by the researcher and there is no financial compensation for the participation in this study.

### POSSIBLE BENEFITS AND RISK

This study will help to increase scientific knowledge about glycaemic index of pumpkin seed incorporated recipes. The risk of participation is minimal as we will use disposable needles, lancets and syringes for withdrawing blood and it will be done by trained technician.

### Confidentiality

Your identity in this study will be treated as confidential. Your personal information will not be shared to anyone but your results will may be published for the scientific purpose.

#### Right to withdraw

Your decision to join this study is voluntary. You may quit at any time without notice. We hope you will take part in this study for entire period because we need all the information for conclusions.

#### **Voluntary Consent**

Your decision to join in this study is voluntary. You may quit at any time for any reason without notice. If you have any questions about any part of there study, you have right to ask PhD student or guide to collect information before you sign this consent form. You should not join any other studies where you would assign to receive any medication, special test or any treatment.

Investigator's statement

I have explained the research programme, purpose of the study and possible benefits and risks of participating in the study. The participant was given an opportunity to discuss the procedures and any other queries.

Signature of the investigator with date

#### **Participant's Statement**

I have clarified that I have read, or had read to me and I understand the description of the study. I voluntarily consent to join in this study.

Signature\_\_\_\_\_

Name\_\_\_\_\_

Date

\*\*\*

### Annexure V

#### CONSENT FORM FOR DETERMINING SATIETY INDEX

# STUDY TITLE: Impact evaluation of pumpkin seeds on glycaemic and lipemic responses of type 2 diabetic old age population of urban Vadodara.

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#### PhD Student

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#### Purpose of the study

Diabetes mellitus is one the major non-communicable diseases. It is the most prevalent metabolic condition and one of the major health problems worldwide. Diabetes mellitus is a growing problem worldwide because of long life expectancy and life style modifications. Diabetes mellitus complications and comorbidities are more frequent in elders compare to young group. One of the pharmacological ways to control blood sugar level is use of botanical products or functional foods. Pumpkin seeds have the potential to reduce glycaemic response. Decreasing the glycaemic index of the diet may improve insulin sensitivity, reducing the risk of diseases. many experiments have concluded that low GI foods are relatively more satiable than their high GI counterpart.

### Protocol of the study

If you decide to join this study, you will be require to consume pumpkin seed incorporated recipe within a span of 20 minutes. You would then be asked to fill out a short form at the end.

#### Costs:

This study only requires your time and cooperation. All the cost will be borne by the researcher and there is no financial compensation for the participation in this study.

### POSSIBLE BENEFITS AND RISK

This study will help to increase scientific knowledge about satiety index of pumpkin seed incorporated recipes. The risk of participation is minimal.

### Confidentiality

Your identity in this study will be treated as confidential. Your personal information will not be shared to anyone but your results will may be published for the scientific purpose.

#### Right to withdraw

Your decision to join this study is voluntary. You may quit at any time without notice. We hope you will take part in this study for entire period because we need all the information for conclusions.

#### **Voluntary Consent**

Your decision to join in this study is voluntary. You may quit at any time for any reason without notice. If you have any questions about any part of there study, you have right to ask PhD student or guide to collect information before you sign this consent form. You should not join any other studies where you would assign to receive any medication, special test or any treatment.

Investigator's statement

I have explained the research programme, purpose of the study and possible benefits and risks of participating in the study. The participant was given an opportunity to discuss the procedures and any other queries.

Signature of the investigator with date

#### **Participant's Statement**

I have clarified that I have read, or had read to me and I understand the description of the study. I voluntarily consent to join in this study.

\*\*\*

Signature\_\_\_\_\_

Name\_\_\_\_\_

Date\_\_\_\_\_

# Annexure VI CONSENT FORM FOR SENSORY EVALUATION

# **STUDY TITLE**: Impact evaluation of pumpkin seeds on glycaemic and lipemic responses of type 2 diabetic old age population of urban Vadodara.

#### PhD Guide

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#### PhD Student

Ms.Nikita Joshi Department of Foods and Nutrition, Faculty of Family and Community sciences, The M S University of Baroda, Vadodara (M):8511220869

# Purpose of the study

Diabetes mellitus is one the major non-communicable diseases. It is the most prevalent metabolic condition and one of the major health problems worldwide. Diabetes mellitus is a growing problem worldwide because of long life expectancy and life style modifications. Diabetes mellitus complications and comorbidities are more frequent in elders compare to young group. One of the pharmacological ways to control blood sugar level is use of botanical products or functional foods. This study has been planned to determine the acceptability of pumpkin seed incorporated recipes.

# Protocol of the study

If you give your consent to join this study, you will be asked to taste pumpkin seed incorporated recipes and carry out the sensory evaluation of the recipes using the hedonic rating scale and composite scoring scale. 7 recipes will be developed by using pumpkin seeds. Sensory evaluation will be carried out on 7 different days.

### Costs

This study only requires your time and cooperation. All the cost will be borne by the researcher and there is no financial compensation for the participation in this study.

### Possible benefits and risk

This study will help to increase scientific knowledge about the taste and overall acceptability of pumpkin seed incorporated recipes. The risk of participation in this study is minimal.

# Confidentiality

Your identity in this study will be treated as confidential. Your personal information will not be shared to anyone but your results will may be published for the scientific purpose.

### Right to withdraw

Your decision to join this study is voluntary. You may quit at any time without notice. We hope you will take part in this study for entire period because we need all the information for conclusions.

### **Voluntary Consent**

Your decision to join in this study is voluntary. You may quit at any time for any reason without notice. If you have any questions about any part of there study, you have right to ask PhD student or guide to collect information before you sign this consent form. You should not join any other studies where you would assign to receive any medication, special test or any treatment.

Investigator's statement

I have explained the research programme, purpose of the study and possible benefits and risks of participating in the study. The participant was given an opportunity to discuss the procedures and any other queries.

Signature of the investigator with date

#### **Participant's Statement**

I have clarified that I have read, or had read to me and I understand the description of the study. I voluntarily consent to join in this study.

Signature\_\_\_\_\_

Date\_\_\_\_\_

Name\_\_\_\_\_

\*\*\*

Name of panelist: _	
Code:	
Date:	

Please choose and mark the statement according to your opinion about the product

Like extremely

Like very much

Like moderately

Like slightly

Neither like nor dislike

**Dislike slightly** 

Dislike moderately

Dislike very much

Dislike extremely

# THE DIABETES DISTRESS SCREENING SCALE

**DIRECTIONS:** Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 2 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 2 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
2. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6

#### DDS

**DIRECTIONS:** Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
2. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
3. Feeling angry, scared, and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
4. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
5. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
6. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6
7. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
8. Feeling that diabetes controls my life.	1	2	3	4	5	6

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
9. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
10. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
11. Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self management.	1	2	3	4	5	6
17. Feeling that friends or family don't give me the emotional support that I would like.	1	2	3	4	5	6

# **DDS17 SCORING SHEET**

#### **INSTRUCTIONS FOR SCORING:**

The DDS17 yields a total diabetes distress scale score plus 4 sub scale scores, each addressing a different kind of distress. To score, simply sum the patient's responses to the appropriate items and divide by the number of items in that scale. The letter in the far right margin corresponds to that item's subscale as listed below. We consider a mean item score of 3 or higher (moderate distress) as a level of distress worthy of clinical attention. Place a check on the line to the far right if the mean item score is  $\geq 3$  to highlight an above-range value.

We also suggest reviewing the patient's responses across all items, regardless of mean item scores. It may be helpful to inquire further or to begin a conversation about any single item scored 3 or higher.

Total DDS Score: a. Sum of 17 item scores. b. Divide by: 17 c. Mean item score: >3 A. Emotional Burden: a. Sum of 5 items (1, 3, 8, 11, 14) b. Divide by: 5 c. Mean item score: > 3**B.** Physician-related Distress: a. Sum of 4 items (2, 4, 9, 15) b. Divide by: 4 c. Mean item score: > 3 C. Regimen-related Distress: a. Sum of 5 items (5, 6, 10, 12, 16) b. Divide by: 5 c. Mean item score: > 3**D.** Interpersonal Distress: a. Sum of 3 items (7, 13, 17) b. Divide by: 3 c. Mean item score: > 3

# THE WORLD HEALTH ORGANIZATION QUALITY OF LIFE (WHOQOL) -BREF

The World Health Organization Quality of Life (WHOQOL)-BREF

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# WHOQOL-BREF

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks**.

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5

20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

# The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

# Do you have any comments about the assessment?

# [The following table should be completed after the interview is finished]

		Equations for computing domain scores	Downagan	Transformed scores*	
		Equations for computing domain scores	Raw score	4-20	0-100
27.	Domain 1	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18		1.	
			a. =	b:	c:
28.	Domain 2	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26)	_	1.	
		$\Box + \Box + \Box + \Box + \Box + \Box$	a. =	b:	c:
29.	Domain 3	Q20 + Q21 + Q22		1	
		$\Box + \Box + \Box$	a. =	b:	c:
30.	Domain 4	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25	_	1	
			a. =	b:	c:

\* See Procedures Manual, pages 13-15

# Mini-Mental State Examination (MMSE)

Patient's Name: \_\_\_\_\_

Date:

# Instructions: Score one point for each correct response within each question or activity.

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day? Month?"
5		"Where are we now? State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then the instructor asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible.
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65,) Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.)
30		TOTAL

# Interpretation of the MMSE:

Method	Score	Interpretation	
Single Cutoff	<24	Abnormal	
21		Increased odds of dementia	
Range	>25	Decreased odds of dementia	
	21	Abnormal for 8 <sup>th</sup> grade education	
Education	<23	Abnormal for high school education	
	<24	Abnormal for college education	
	24-30	No cognitive impairment	
Severity	18-23	Mild cognitive impairment	
	0-17	Severe cognitive impairment	

# Interpretation of MMSE Scores:

Score	Degree of Impairment	Formal Psychometric Assessment	Day-to-Day Functioning
25-30	25-30 Questionably significant If clinical signs of cognitive impairment are present, formal assessment of cognition may be valuable.		May have clinically significant but mild deficits. Likely to affect only most demanding activities of daily living.
20-25	Mild	Formal assessment may be helpful to better determine pattern and extent of deficits.	Significant effect. May require some supervision, support and assistance.
10-20	10-20ModerateFormal assessment may be helpful if there are specific clinical indications.		Clear impairment. May require 24-hour supervision.
0-10	Severe	Patient not likely to be testable.	Marked impairment. Likely to require 24-hour supervision and assistance with ADL.

Source:
Folstein MF, Folstein SE, McHugh PR: "Mini-mental state: A practical method for grading the cognitive state of patients for the clinician." J Psychiatr Res 1975;12:189-198.

	GNITIVE ASSESSMENT riginal Version	(MOCA)	Edu	NAME : acation : Sex :	Da	ate of birt DAT		
VISUOSPATIAL / EX (5) (1) Begin (C)	A B 2 4 3		Copy cube	Draw C ( 3 point:	LOCK (Ter	n past elev	ren)	POINTS
)	[]		[]	[ ] Contour	[ Numl	] bers	[ ] Hands	/5
NAMING				E Jane				/3
<b>M E M O R Y</b> repeat them. Do 2 trials Do a recall after 5 minu	Read list of words, subject mus s, even if 1st trial is successful. ites.	t FA 1st trial 2nd trial	CE VELV	/ET CHU	JRCH	DAISY	RED	No points
ATTENTION	Read list of digits (1 digit/ sec.).	Subject has to re Subject has to rep				] 2 1 ] 7 4	854 2	/2
Read list of letters. The	subject must tap with his hand a		nts if ≥2 errors CMNAAJH	KLBAFAK	DEAAA	JAMOF	AAB	/1
Serial 7 subtraction sta	rting at 100 [ ] 93		[]7	9 [	] 72	[]	65	/3
LANGUAGE	Repeat : I only know that John The cat always hid ur		y. [ ]					/2
Fluency / Name r	naximum number of words in on	e minute that begin wi	th the letter F	[	[]	_ (N ≥ 11 v	vords)	/1
ABSTRACTION	Similarity between e.g. banana -	orange = fruit [	] train – bicy	/cle [] w	vatch - rule	er		/2
DELAYED RECALL Optional	WITH NO CUE         [           Category cue         [	ACE VELVET ] [ ]	CHURCH [ ]	DAISY [ ]		Points for UNCUED recall only		/5
	Multiple choice cue	ath []Var		. г		[ ] ]	it.	16
ORIENTATION	[]Date []Moi	nth []Year	[ ] Da		] Place	[ ]C	ity	/6
© Z.Nasreddine MD Administered by:	, vvv		, Norm	nal ≥26/30	101/12	ld 1 point if	_ ≤ 12 yr edu	_/30

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MEMORY repeat them. Do 2 trial Do a recall after 5 minu	Read list of words, subjec s, even if 1st trial is successful. ıtes.	F	1st trial 2nd trial	TRUCK	BANA	NA	VIOLIN	DESI	K GREEN	No points
ATTENTION	Read list of digits (1 digit,	/ sec.).	Subject has t Subject has t					[]3	3 2 9 6 5 3 5 2	_/2
Read list of letters. The	subject must tap with his l	nand at eacl					FAKDE		ΛΟΓΑΑΒ	/1
Serial 7 subtraction sta	arting at 90 [	] 83	[]	76	[]6	9	[]6	2	[ ] 55	/3
LANGUAGE	Repeat : A bird can fly int	o closed wi	ndows when	it's dark ar	nd windy.	[]	rect: <b>2 pts</b> , 1	correct: <b>1 pt</b> ,	0 correct: <b>0 pt</b>	<u> </u>
Fluency / Name	The caring gran maximum number of words						[ ]	(N ≥	11 words)	/2 _/1
ABSTRACTION	Similarity between e.g. ca		-			ruby	[ ] canno			/2
DELAYED RECALL	Has to recall words WITH NO CUE	TRUCK	BANAN []		OLIN	DES [ ]			ED	/5
Optional	Category cue Multiple choice cue								a	
ORIENTATION		] Month	[]Y	ear	[ ] Day	у	[ ] Pla	ce [	] City	/6
Adapted by : Z. Nasr © Z.Nasreddine	eddine MD, N. Phillips P				Norm	al ≥2	6 / 30 T(	DTAL	-	/30
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DÉNOMINAT					The second			/3
<b>M É M O I R E</b> Faire 2 essais mêm Faire un rappel 5 m	Lire la liste de mots, le patient doit répéter. le si le 1er essai est réussi. nin après.	1 <sup>er</sup> essai 2 <sup>ème</sup> essai	VISAGE	VELOURS	ÉGLISE	MARGUERITE	ROUGE	Pas de point
ATTENTION	Lire la série de chiffres (1	chiffre/ sec.).		•	oit la répéter. ter à l'envers.	[ ] 2 1 8 5 [ ] 7 4 2	4	_/2
Lire la série de lettre	es. Le patient doit taper de l	a main à cha		-		( D E A A A J A N	NOFAAB	/1
Soustraire série de 7	y à partir de 100. [	] 93 4 ou 5 soustra	[ ] 86 ctions correctes	[ ] 79 5: <b>3 pts</b> , 2 ou 3 o	-	] <b>72</b> [ , 1 correcte : <b>1 pt</b> , o c	] 65 correcte : 0 pt	/3
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Fluidité de langage. ABSTRACTION	Nommer un maximum de					• • <u> </u>	≥11 mots)	/1
	Similitude entre ex : ban	-		-		-	Defete	/2
	Doit se souvenir des mots SANS INDICES Indice de catégorie	VISAGE []	VELOURS	ÉGLISE	MARGUER	RITE ROUGE	Points pour rappel SANS INDICES seulement	/5
Optionnel	Indice choix multiples							
ORIENTATION	[]Date [	] Mois	[ ] Ann	ée []	Jour [	] Endroit [	] Ville	/6
© Z.Nasreddine MD		www.mo	ocatest.org	Noi	rmal ≥ 26 / 30	TOTAL		_/30
Administré par :				_		Ajouter 1 point	si scolarité ≤	12 ans

#### THE MODIFIED MINI-MENTAL STATE EXAMINATION

#### **Exhibit 8.9** The Modified Mini-Mental State Test

Note: alternatives printed in parentheses after items 6 and 10 may be used for people in institutional care settings

#### THE 3MS

Now I am going to ask some questions of a different kind. Some of the questions that I ask you will be easy; others may be more difficult. They are all routine questions that we ask of everyone. I may also ask you the same question twice. Just answer all of them as best you can.

	VVIILIN I	AND WHI		RN? Da	dd	/ mmy		Place		city/	town		province
5	Day	$\mathbf{G}$	0 <b>G</b>		uu	iiiii y	ууу			city/	lown		province
	Ν	Aonth	1 <b>G</b>	$_0$ G		Tow	n		I <b>G</b>	$_0$ G			
	Year	1 <b>G</b>	$_0  \mathbf{G}$		Provi	nce	1 <b>C</b>	6	$_0  {f G}$				
2	THREE	WORDS	(Num	ber of p	resentati	ions	_)						
3	Shoes	1 <b>G</b> 0 <b>G</b>	ì	Blue	1 <b>G</b>	$_0\mathbf{G}$			Mod	esty	$\mathbf{G}$	0 <b>G</b>	
3	COUNT	ING and V	VORLD	BACK	WARD	S							
7	COUNTIN	G FORWAR	.DS	Can d	0	Can'	t						
		te their answe											
	<b>5 10 1</b> (with	te then answe	5	4	3	2 1							
	Score 0	G 1G	$_{2}\mathbf{G}$										
	SPELL "W			Can c	d	Can	't						
			• • • • • •	Call	10	Can	ι						
	"World" ba	ackwards (pr	int letters)	 D	 L	– R	0	W					
	C .	~ ~	6		_								
	Score 0	G 1G	$_{2}\mathbf{G}$	3 <b>G</b>	${}_4\mathbf{G}$	5 <b>G</b>	67 <b>G</b> I	Not cor	npleted: S	ubject can'	t read		
<b>4.</b>	FIRST R	ECALL											
9													
	Spontaneou	s recall: Sho	es			3 <b>G</b>							
	-	is recall: Sho thing to wea			$_2$ <b>G</b>	3 <b>G</b>							
	Cue: Some	is recall: Shoo thing to wea Shirt, shoes, s	r		$_2$ <b>G</b>	3 <b>G</b> 1 <b>G</b>							
	Cue: Some	thing to wea Shirt, shoes, s	r		2 <b>G</b>								
	Cue: Some Multiple: S Missed con	<b>thing to wea</b> S <b>hirt, shoes,</b> s npletely	r socks		2 <b>G</b>	1 <b>G</b> 0 <b>G</b>							
	Cue: Somet Multiple: S Missed con Spontaneou	thing to wea Shirt, shoes, s npletely as recall: Blue	r socks		2 <b>G</b>	1 <b>G</b> 0 <b>G</b> 3 <b>G</b>							
	Cue: Somet Multiple: S Missed con Spontaneou Cue: A colo	thing to wea Shirt, shoes, s npletely as recall: Blue	r socks		2 <b>G</b>	1 <b>G</b> 0 <b>G</b>							
	Cue: Somet Multiple: S Missed con Spontaneou Cue: A colo	thing to wea Shirt, shoes, s npletely is recall: Blue Dur Black, brown,	r socks		2 <b>G</b>	1 <b>G</b> 0 <b>G</b> 3 <b>G</b> 2 <b>G</b>							
	Cue: Somet Multiple: S Missed com Spontaneou Cue: A colo Multiple: B Missed com Spontaneou	thing to wea shirt, shoes, shift, shoes, shift, shoes, sho	r socks , blue esty		2 <b>G</b>	1 G 0 G 3 G 2 G 1 G 0 G 3 G							
	Cue: Somet Multiple: S Missed con Spontaneou Cue: A colo Multiple: B Missed con Spontaneou Cue: A goo	thing to wea (hirt, shoes, shoes, shoes) appletely as recall: Blue our Black, brown, appletely	r socks , blue esty uality	ty.	2 <b>G</b>	1 <b>G</b> 0 <b>G</b> 3 <b>G</b> 2 <b>G</b> 1 <b>G</b> 0 <b>G</b>							

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# 5. \_\_\_\_\_ TODAY'S DATE

15								
	Today's date		. C	Month		. C		
	Accurate Missed by 1 or 2 days		3 <b>G</b> 2 <b>G</b>	Accurate or within 5 days Missed by 1 month	5	2 G 1 G		
	Missed by 1 of 2 days Missed by 3-5 days		2 G 1 G	Missed by more than a m	onth	0 G		
				wissed by more than a m	onui	0 0		
	Missed by more than 5 d	ays	0 <b>G</b>					
	Year Accurate		8 <b>G</b>	Day of week		1 <b>G</b>		
			8 G 4 G	Missed		0 <b>G</b>		
	Missed by 1 year Missed by 2-5 years		4 G 2 G	Wilsseu		0 <b>G</b>		
	Missed by more than 5 ye	ears	0 <b>G</b>					
	Season Accurate or within a mon	41-	. 6					
		th	1 <b>G</b>					
	Missed		0 <b>G</b>					
<b>6</b>	SPATIAL ORIENTATIO	ON						
5	Province	2 <b>G</b>	0 <b>G</b>	Country 1 G	0 <b>G</b>			
	City or town	1 <b>G</b>	0 <b>G</b>	Hosp., store, home	1 <b>G</b>	0 <b>G</b>		
		6	<u> </u>	<u>G</u> , , ,	C	6		
	*MMSE: Number	G y	<b>G</b> N	Street (Floor)	<b>G</b> Y	<b>G</b> N		
	(Place)			(Floor)				
7	NAMING							
5	Forehead	1 <b>G</b>	0 <b>G</b>	Elbow	1 <b>G</b>	0 <b>G</b>		
	Chin	1 <b>G</b>	0 <b>G</b>	Knuckle	1 <b>G</b>	0 <b>G</b>		
	Shoulder	1 <b>G</b>	0 <b>G</b>					
	*MMCE <b>D</b>	6	C	XX7-4-1.	6	<u> </u>		
	*MMSE: <b>Pencil</b>	G y	<b>G</b> N	Watch	<b>G</b> Y	<b>G</b> N		
	Not completed: Subject b	11nd 66 <b>(</b>	2					
8	FOUR-LEGGED ANIMA	ALS (W	rite animals named	) $\bigcirc$ (Timed item)	(30 se	conds)		
10						,		
		,					,	
		,	,				7	
		,		,			,	
		,		;				

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9.		SIMILARITIES	(Write answer)
----	--	--------------	----------------

6

Arm-leg	
Limbs, extremities	2 <b>G</b>
Body parts, bend, move, joint	1 <b>G</b>
Very weak similarity or no similarity	0 <b>G</b>
Laughing-crying	
Feeling, emotion	2 <b>G</b>
Expressions, sounds, relieve tension	1 <b>G</b>
Very weak similarity or no similarity	0 <b>G</b>
Eating-sleeping	
Necessary bodily functions	2 <b>G</b>
Bodily functions, relaxing, good for you	1 <b>G</b>
Very weak similarity or no similarity	0 <b>G</b>

# 10. \_\_\_\_ REPETITION

I would like	to go home	e (out)	
Correct 1 or 2 missed More than 2 r	U		2 <b>G</b> 1 <b>G</b>
No ifs ands or buts	1 G 1 G 1 G	0 G 0 G 0 G	

11 READ AND OBEY "CLOSE YOUR EYES"	(Use Cue Card)
Obeys without prompting	3 <b>G</b>
Obeys after prompting	2 <b>G</b>
Read aloud only	1 <b>G</b>
None of the above	0 <b>G</b>
Not completed: subject blind	66 <b>G</b>
subject illiterate	67 <b>G</b>

12	WRITING	Ø	(Timed	l item)	(	1 min	ute)	
5	(I) would like to go home	(out)	0 <b>G</b>	1 <b>G</b>	2 <b>G</b>	3 <b>G</b>	4 <b>G</b>	5 <b>G</b>
	*MMSE: Sentence Not completed:	-	<b>G</b> N physicall	y unable	66 67			
	Note handedness	L 2		This is u		-	l, below	')

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0 **G** 

<b>13.</b> COPYING TWO PENTAGONS	$\bigcirc$	(Timed item)	(1 minute)
10			

10

#### Editor:

#### Note that there is a little diagram to include here: the two overlapping pentangles (camera-ready, and same as in 2<sup>nd</sup> edition, page 316, near bottom of page)

	Pentagon 1	Pentagon 2
5 approx equal sides	4 <b>G</b>	4 <b>G</b>
5 unequal (2:1) sides	3 <b>G</b>	3 <b>G</b>
Other enclosed figures	2 <b>G</b>	2 <b>G</b>
2 or more lines	1 <b>G</b>	1 <b>G</b>
Less than 2 lines	0 <b>G</b>	0 <b>G</b>
	Intersection	
4 corners	2 <b>G</b>	
Not 4 corner enclosure	1 <b>G</b>	
No intersection or no enclosure	0 <b>G</b>	
Not completed: Physically unable	66 <b>G</b>	
14 THREE STAGE COMMANN	,	
Take this paper with your		
Left/right hand	1 <b>G</b> 0 <b>G</b>	
fold it in half	1 <b>G</b> 0 <b>G</b>	
and hand it back to me	0 <b>G</b> 66 <b>G</b> Physically u	11

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#### THE MODIFIED MINI-MENTAL STATE EXAMINATION

15	SECOND RECALL		
9	Spontaneous recall: Shoes		3 <b>G</b>
	Cue: Something to wear	2 <b>G</b>	
	Multiple: Shirt, shoes, socks		1 <b>G</b>
	Missed completely		0 <b>G</b>
	Spontaneous recall: Blue		3 <b>G</b>
	Cue: A colour		2 <b>G</b>
	Multiple: Black, brown, blue		1 <b>G</b>
	Missed completely		0 <b>G</b>
	Spontaneous recall: Modesty		3 <b>G</b>
	Cue: A good personal quality		2 <b>G</b>
	Multiple: Modesty, charity, honesty		1 <b>G</b>
	Missed completely		0 <b>G</b>

### **3MS TOTAL SCORE**

The 3MS test as administered in the Canadian Study of Health and Aging. Adapted from an original provided by Dr. E. Teng. With permission.



## **Instructions for Administration & Scoring**

ID: \_\_\_\_\_ Date: \_\_\_\_\_

### **Step 1: Three Word Registration**

Look directly at person and say, "Please listen carefully. I am going to say three words that I want you to repeat back to me now and try to remember. The words are [select a list of words from the versions below]. Please say them for me now." If the person is unable to repeat the words after three attempts, move on to Step 2 (clock drawing).

The following and other word lists have been used in one or more clinical studies.<sup>1-3</sup> For repeated administrations, use of an alternative word list is recommended.

Version 1	Version 2	Version 3	Version 4	Version 5	Version 6
Banana	Leader	Village	River	Captain	Daughter
Sunrise	Season	Kitchen	Nation	Garden	Heaven
Chair	Table	Baby	Finger	Picture	Mountain

#### Step 2: Clock Drawing

Say: "Next, I want you to draw a clock for me. First, put in all of the numbers where they go." When that is completed, say: "Now, set the hands to 10 past 11."

Use preprinted circle (see next page) for this exercise. Repeat instructions as needed as this is not a memory test. Move to Step 3 if the clock is not complete within three minutes.

#### Step 3: Three Word Recall

Ask the person to recall the three words you stated in Step 1. Say: "What were the three words I asked you to remember?" Record the word list version number and the person's answers below.

Word List Version: \_\_\_\_\_ Person's Answers: \_\_\_\_\_

#### Scoring

Word Recall: (0-3 points)	1 point for each word spontaneously recalled without cueing.
Clock Draw: (0 or 2 points)	Normal clock = 2 points. A normal clock has all numbers placed in the correct sequence and approximately correct position (e.g., 12, 3, 6 and 9 are in anchor positions) with no missing or duplicate numbers. Hands are pointing to the 11 and 2 (11:10). Hand length is not scored. Inability or refusal to draw a clock (abnormal) = 0 points.
Total Score: (0-5 points)	Total score = Word Recall score + Clock Draw score. A cut point of <3 on the Mini-Cog™ has been validated for dementia screening, but many individuals with clinically meaningful cognitive impairment will score higher. When greater sensitivity is desired, a cut point of <4 is recommended as it may indicate a need for further evaluation of cognitive status.

ID:\_\_\_\_\_

Date: \_

#### References

- 1. Borson S, Scanlan JM, Chen PJ et al. The Mini-Cog as a screen for dementia: Validation in a population-based sample. J Am Geriatr Soc 2003;51:1451–1454.
- 2. Borson S, Scanlan JM, Watanabe J et al. Improving identification of cognitive impairment in primary care. Int J Geriatr Psychiatry 2006;21: 349–355.
- 3. Lessig M, Scanlan J et al. Time that tells: Critical clock-drawing errors for dementia screening. Int Psychogeriatr. 2008 June; 20(3): 459–470.
- 4. Tsoi K, Chan J et al. Cognitive tests to detect dementia: A systematic review and meta-analysis. JAMA Intern Med. 2015; E1-E9.
- 5. McCarten J, Anderson P et al. Screening for cognitive impairment in an elderly veteran population: Acceptability and results using different versions of the Mini-Cog. J Am Geriatr Soc 2011; 59: 309-213.
- 6. McCarten J, Anderson P et al. Finding dementia in primary care: The results of a clinical demonstration project. J Am Geriatr Soc 2012; 60: 210-217.
- 7. Scanlan J & Borson S. The Mini-Cog: Receiver operating characteristics with the expert and naive raters. Int J Geriatr Psychiatry 2001; 16: 216-222.

# AD8 Dementia Screening Interview

Patient ID#:	
CS ID#:	
Date:	

Remember, "Yes, a change" indicates that there has been a change in the last several years caused by cognitive (thinking and memory) problems.	YES, A change	NO, No change	N/A, Don't know
<ol> <li>Problems with judgment (e.g., problems making decisions, bad financial decisions, problems with thinking)</li> </ol>			
2. Less interest in hobbies/activities			
<ol> <li>Repeats the same things over and over (questions, stories, or statements)</li> </ol>			
<ol> <li>Trouble learning how to use a tool, appliance, or gadget (e.g., VCR, computer, microwave, remote control)</li> </ol>			
5. Forgets correct month or year			
<ol> <li>Trouble handling complicated financial affairs (e.g., balancing checkbook, income taxes, paying bills)</li> </ol>			
7. Trouble remembering appointments			
<ol> <li>Daily problems with thinking and/or memory</li> </ol>			
TOTAL AD8 SCORE			

Adapted from Galvin JE et al, The AD8, a brief informant interview to detect dementia, Neurology 2005:65:559-564 Copyright 2005. The AD8 is a copyrighted instrument of the Alzheimer's Disease Research Center, Washington University, St. Louis, Missouri. All Rights Reserved.

#### The AD8 Administration and Scoring Guidelines

A spontaneous self-correction is allowed for all responses without counting as an error.

The questions are given to the respondent on a clipboard for self–administration or can be read aloud to the respondent either in person or over the phone. It is preferable to administer the AD8 to an informant, if available. If an informant is not available, the AD8 may be administered to the patient.

When administered to an informant, specifically ask the respondent to rate change in the patient.

When administered to the patient, specifically ask the patient to rate changes in his/her ability for each of the items, *without* attributing causality.

If read aloud to the respondent, it is important for the clinician to carefully read the phrase as worded and give emphasis to note changes due to cognitive problems (not physical problems). There should be a one second delay between individual items.

No timeframe for change is required.

The final score is a sum of the number items marked "Yes, A change".

**Interpretation of the AD8** (Adapted from Galvin JE et al, The AD8, a brief informant interview to detect dementia, Neurology 2005:65:559-564)

A screening test in itself is insufficient to diagnose a dementing disorder. The AD8 is, however, quite sensitive to detecting early cognitive changes associated many common dementing illness including Alzheimer disease, vascular dementia, Lewy body dementia and frontotemporal dementia.

Scores in the impaired range (see below) indicate a need for further assessment. Scores in the "normal" range suggest that a dementing disorder is unlikely, but a very early disease process cannot be ruled out. More advanced assessment may be warranted in cases where other objective evidence of impairment exists.

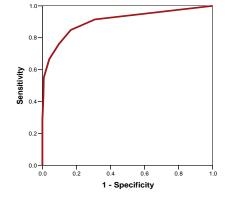
Based on clinical research findings from 995 individuals included in the development and validation samples, the following cut points are provided:

- 0 1: Normal cognition
- 2 or greater: Cognitive impairment is likely to be present

Administered to either the informant (preferable) or the patient, the AD8 has the following properties:

- Sensitivity > 84%
- Specificity > 80%
- Positive Predictive Value > 85%
- Negative Predictive Value > 70%
- Area under the Curve: 0.908; 95%CI: 0.888-0.925

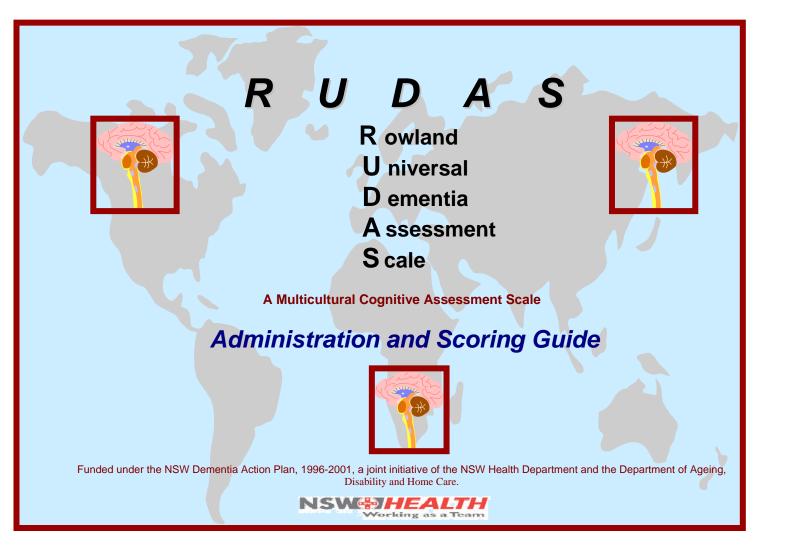
Reciever Operator Characteristics (ROC) curve for AD8



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#### **Introduction**

The Rowland Universal Dementia Assessment Scale (RUDAS): A Multicultural Cognitive Assessment Scale – (Storey J, Rowland J, Basic D, Conforti D & Dickson H [2004] *International Psychogeriatrics*, 16(1) 13-31) is a short cognitive screening instrument designed to minimise the effects of cultural learning and language diversity on the assessment of baseline cognitive performance.

When administering the RUDAS it is important that the respondent is encouraged to communicate in the language with which they are most competent and comfortable.

Test administrators should read the following instructions carefully before using the RUDAS.

#### The Assessment Context – General Guidelines:

#### **Test Anxiety**

• Make sure the test taker is as relaxed as possible, as test anxiety can interfere with performance on cognitive tests.

#### Hearing

Conduct the RUDAS in a quiet area and make sure the test taker can hear clearly. It is
important to identify at the beginning of the assessment if the test taker has impaired
hearing and accommodate for this as much as possible by speaking slowly and clearly.
Encourage the test taker to wear any hearing aids. Be careful not to speak too loudly as
this may result in distortion. (There is a large print version of the RUDAS for test takers
with severe hearing impairment).

#### Vision

• Ensure that the test taker is using reading glasses where necessary and that there is sufficient light in the room.

#### Seating

• Sit opposite the test taker. This is important for communication reasons as well as controlling for the difficulty of some items on the RUDAS. Do not sit behind a desk, as this will inhibit the giving of instructions for some items on the RUDAS and may also be intimidating for the test taker.

#### **Recording Responses**

• It is important to record the test taker's full response to each item.

#### **Physical Disability**

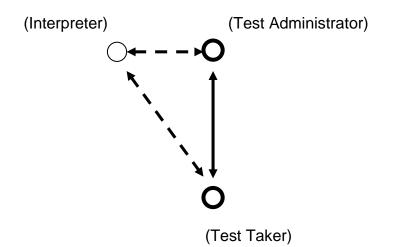
 For test takers who have a physical disability (e.g. vision, hearing, hemiparesis, amputee, stroke, aphasia) which may affect their ability to perform certain items on the RUDAS, it is important to complete the RUDAS as fully as possible but to interpret any total score less then 22 with caution (further research is necessary to assess validity of the RUDAS in this sub-group of patients)

#### The Language/ Cultural Context:

#### Using a Professional Interpreter

If you are utilising a professional interpreter to administer the RUDAS it is important to consider the following:

- 1. Interpreters should be used in all situations where the test taker's preferred language is not spoken fluently by the test administrator.
- 2. Make sure that the language spoken by the interpreter (including the dialect) is the same one with which the test taker is familiar.
- 3. It is important to explain to the test taker that the interpreter is the facilitator and that you will be asking the questions. This may help to avoid confusion during the assessment.
- 4. It is better for the interpreter to sit next to the test administrator while the test taker sits opposite. This will reinforce the adjunctive role of the interpreter and make it easier for the test taker to synthesise the non-verbal cues from the test administrator and the verbal cues from the interpreter.



- 5. It is important to brief the interpreter before starting the assessment:
- The interpreter should be aware of the general nature of the interaction i.e. that it is a cognitive assessment
- Remind the interpreter of the importance of concurrent and precise interpreting. Explain that your instructions and the test taker's responses should be interpreted as exactly as possible.
- Ask the interpreter to take note of any instances during the assessment where the test taker's performance may have been affected by subtle or unintended changes to the meaning of the test instructions due to language or cultural factors
- Inform the interpreter that it may be necessary at the end of the test for you to clarify a
  concept covered in the assessment to further make the distinction between the test
  taker's actual cognitive capacity and potential cultural bias which may arise as a result of
  the translation process.

#### **Multilingual Test Administrators**

If, as the test administrator, you are multilingual it is important to consider all of the same issues which are relevant to the use of a professional interpreter, as well as the following:

- You may need to be careful when translating the RUDAS questions as you might find it more difficult when you have to read in one language and speak in another.
- It is important that you translate the RUDAS questions precisely. Be aware of the differences between formal and informal word usage when translating the RUDAS instructions and recording the test taker's responses.

# Item 1 – Memory

#### **Grocery List**

1. I want you to imagine that we are going shopping. Here is a list of grocery items. I would like you to remember the following items which we need to get from the shop. When we get to the shop in about 5 minutes time I will ask you what it is that we have to buy. You must remember the list for me.

Tea Cooking Oil Eggs Soap

Please repeat this list for me (Ask person to repeat the list 3 times). (If person did not repeat all four words, repeat the list until the person has learned them and can repeat them, or, up to a maximum of five times.)

- Important to give enough learning trials so that test taker registers and retains the list as well as they can (max. of 5 learning trials)
- Ask the test taker to repeat the list back to you at least three times until they can repeat it correctly or as well as they are going to
- Use realistic nature of the scenario and a little humour (if appropriate) to build rapport and make the task less confrontational i.e. WE are going shopping; I am relying on YOU to remember the list FOR ME, so don't forget. When WE get to the shop . . .
- To facilitate learning of the list, use your fingers to list off items on the list when teaching it to the test taker to make the task as concrete as possible e.g. thumb = tea, index finger = cooking oil etc.

#### Scoring:

This is the learning part of the memory question. There are no points for this part of the question but the memory recall component later in the test has a maximum score of 8 points.

Item 2 - Body C	Drientation
-----------------	-------------

# **Body Orientation**

>

<ul> <li>I am going to ask you to identify/show me different parts of the body. (Correct = 1, Incorrect = 0).</li> </ul>		
Once the person correctly answers 5 parts of this question, do not continue as the maximum score is 5.		
(1) show me your right foot	1	
(2) show me your left hand	1	
(3) with your right hand touch your left shoulder	1	
(4) with your left hand touch your right ear	1	
(5) which is (point to/indicate) my left knee	1	
(6) which is (point to/indicate) my right elbow	1	
(7) with your right hand point to/indicate my left eye	1	
(8) with your left hand point to/indicate my left foot	1	
		/5

- Important to sit opposite the test taker (controls for difficulty of the tasks)
- There doesn't need to be a lot of explanation before starting, just say "I am going to ask you to indicate various parts of the body . . ." the task is explicit as it evolves

#### Scoring:

- Although there are 8 parts, this item has a maximum score of 5 points. Once the test taker has 5 correct answers there is no need to continue.
- Be careful with scoring remember you are sitting opposite the test taker it is easy to make mistakes so concentrate to make sure you score the person accurately
- There are no half marks, the test taker must get each task 100% correct to be marked correct (e.g. if test taker is asked "with your right hand indicate my left eye" and they use their left hand but still point to your left eye mark as incorrect)

Item 3 - Praxis					
Fist / Palm					
watch me and co put one hand in a and then alternate doing this action	w you an action/exercise with my hands. I want you to by what I do. Copy me when I do this (i.e. demonstrate ist, and the other hand palm down on the table or your knees simultaneously.) Now do it with me. I would like you to ke at this pace until I tell you to stop - approximately 10 seconds. (Demonstrate at moderate walking pace).	eep			
Score as:					
Score as: Normal	<ul> <li>2 (very few if any errors; self-corrected; progressivel, better; good maintenance; only very slight lack of synchrony between hands)</li> </ul>	ly			
		ly			

- It is important to sit opposite the test taker (controls for difficulty of the task)
- When teaching the task use the following steps:

**Step 1:** I want you to put your hands on your knees like this (i.e. put both your hands palm down on your knees (i.e. if no table surface)

**Step 2:** Now watch carefully as I do this (put one hand in a fist in the vertical position and leave the other hand palm down) - I want you to do this just like I did.

**Step 3:** Watch me again now as I am doing this (alternate hands simultaneously - one in a fist and the other palm down and keep alternating for 5 - 6 trials).

**Step 4:** Ask test taker to copy exactly what you are doing. If test taker is confused and has not learned the task successfully then repeat Steps 1, 2 and 3

**Step 5:** Once test taker has learned the task (i.e. understands as well as possible what they are meant to do - regardless of whether or not they can do it 100%), ask them to repeat the exercise at the pace you demonstrate until you tell them to stop (now demonstrate task - intervals between change of hands should reflect moderate walking pace). Do not allow the test taker to copy you when scoring – must demonstrate the task independently

#### Scoring:

This question has a maximum score of 2 points.

In order to help distinguish between the three levels of competence, refer to the following:

Score	Fist / Palm Integrity	No. of Errors	Fluency	Ability to Self- Correct	Progressive Improvement	Synchrony
Normal	Good adherence to 'palm down' and 'fist' actions with few intrusions or incorrect variations	Minimal	Good	Good	Clearly evident	Only very slight lack of synchrony
Partially Adequate	Obvious intrusions and incorrect variations in 'palm down' and 'fist' actions	Noticeable	Some attempt to maintain	Some attempt	Some indication	May be noticeable lack of synchrony
Failed	Barely able to identify correct 'palm down' and 'fist' actions because of many intrusions and incorrect variations	Many	Poor or none	None	Very little or none	Little or no synchrony

#### Normal

A person who performs normally on this task should exhibit signs of intact learning and should be able to replicate clearly, the 'fist in the vertical position' and 'palm down' actions. Their performance on the task should improve with progressive learning trials to a point where they can do the task fluently with minimal errors. The test taker should demonstrate the ability to self- correct, show progressive improvement over the course of the task and have only very slight lack of synchrony between the hands.

#### **Partially Adequate**

A person whose response is partially adequate will make noticeable errors e.g. occasionally places palm up instead of palm down or may place palm up instead of converting to the fist or may form the fist in the horizontal position. They may have to stop occasionally in order to self-correct but even if they are unable to perform the task perfectly there should be some evidence that they have learned the task, some attempt to self-correct and some indication of an attempt to maintain the fluency of the alternating hands. There may be a noticeable lack of synchrony between the hands.

#### Failed

A person who fails this task shows very little if no ability to understand and execute the task. There are many errors, very little or no evidence of improvement, inability to self-correct, poor maintenance, and obvious inability to emulate correct hand positions and to perform the simultaneous changing of hands with any synchrony. A person who fails may not be able to form a fist or distinguish between palm up and palm down, may not alternate the actions across hands and may not be able to use both hands together at all.

Item 4 - Drawing		
Visuo-Constructional Cube Drawing	]	
<ul> <li>4. Please draw this picture exactly as it looks to you (Show cube on back of page). (Yes = 1; No = 0)</li> <li>Score as:</li> </ul>	K	
(1) Has person drawn a picture based on a square?	1	
(2) Do all internal lines appear in person's drawing?	1	
(3) Do all external lines appear in person's drawing?	1 <i>I</i> :	3

This question has a maximum of 3 points.

- Show test taker cue card of cube drawing
- If there is no cue card, the test administrator can draw the cube onto plain (not lined) paper.
- Make sure that test taker can see the drawing clearly (check that they are wearing prescription glasses if applicable)
- Ask test taker to draw the picture of the cube as well as they can

#### Scoring:

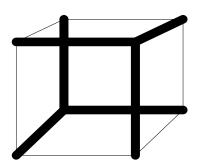
Has test taker drawn a picture based on a square? (i.e. There is a square somewhere in the drawing)

YES / NO

Do all internal lines (i.e. dark lines) appear in test taker's drawing?

YES / NO

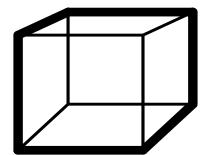
i.e.



Do all external lines (i.e. dark lines) appear in test taker's drawing?

YES / NO

i.e.



# Item 5 - Judgement

### **Judgement - Crossing the Street**

5. You are standing on the side of a busy street. There is no pedestrian crossing and no traffic lights. Tell me what you would do to get across to the other side of the street safely. (If person gives incomplete answer use prompt: "Is there anything else you would do?") Record exactly what patient says and circle all parts of response which were prompted.
Score as:
Did person indicate that they would look for traffic?
(YES = 2; YES PROMPTED = 1; NO = 0)
Did person make any additional safety proposals?
....2

- If the test taker gives no response to the question or says "I don't know", then repeat the question once only.
- Except where the test taker answers both parts of the question on the first attempt, use the prompt 'Is there anything else you would do' in all situations. This is to gain as complete a response as possible from the test taker.
- Use only the general prompt 'Is there anything else you would do' do not prompt the person in any other way
- Record test taker's response to this question.
- Circle any part of test taker's response which was prompted and score accordingly.
- If the test taker says that they never cross the road by themselves (e.g. they are in a wheelchair or their eyesight is poor), then ask them the question again but modify as follows:

"What would anyone who wanted to cross the road have to do to get across safely?"

#### Scoring:

This item has a maximum score of 4 points. Each of the two parts:

- 1. look for traffic, and
- 2. additional safety proposal

has a total score of 2 points i.e. Yes = 2; Yes Prompted = 1; No = Zero

i.e.

• Did test taker indicate that they would look for traffic?

YES / YES PROMPTED / NO 2 1 0

Examples of Correct Responses	Examples of Incorrect Responses
I would look for traffic.	Just go across.
Look left and right.	Put my hand up so the traffic knows I want to
	Cross.
Check the cars.	Go to the corner and cross.
Check that it's clear.	Wave at the cars so they can see me.
Go across when there is nothing coming.	I wouldn't go across.

• Did test taker make any additional safety proposals in road crossing scenario?

YES / YES PROMPTED / NO 2 1 0

Examples of Correct Responses	Examples of Incorrect Responses	
Cross to the middle of the road and then look	Run as fast as I can.	
again to make sure there was no traffic before		
going right across.		
Keep looking for traffic while crossing.	Cross when the walk sign is green.	
Go across quickly but without running.	Cross at the crossing.	
Be careful.	Just put my head down and go.	
Wait till I could cross with some other people.		
Ask for help.		

#### Scoring Examples:

#### Example 1

"I don't know. (Repeat the question).

"I'd look for the cars. (I can't think of anything else except be careful.")

This response would score 3 points out of a total of 4 because the person said that they would look for the cars (2/2) and when prompted (i.e. circle indicates that it was prompted) said that they would be careful (1/2) i.e. 2/2 + 1/2 = 3/4

#### Example 2

"Just go across. Check for the cars."

This response would score 1 point only out of a total of 4 because the first part of the answer 'just go across' was incorrect (0/2), and the second part of the answer 'check for the cars' while correct, was prompted (i.e. because it was circled to indicate that it was prompted) (1/2) i.e. 0/2 + 1/2 = 1/4

#### Example 3

"Put my hand up so the traffic knows I want to cross and then walk to the middle of the road before going right across."

This response would score 2 points out of a total of 4 because the first part of the answer is incorrect (0/2) and the second part of the answer 'then walk to the middle of the road before going right across' is correct (2/2) i.e. 0/2 + 2/2 = 2/4

# Item 1 – Memory

## Memory Recall (Item 1 Revisited - 4 Grocery Items)

1. We have just arrived at the shop. (Can you remember the list of groceries we need to buy? (Prompt: If person cannot recall any of the list, say "The first one was 'tea'."		
(Score 2 points each for any item recalled which was not prompted.)		
Circle 'Tea' if used as a prompt and score as 0 out of 2)		
Tea	2	
Cooking Oil	2	
Eggs	2	
Soap	2	
		/8

- Ask test taker to repeat the 4 items on the grocery list
- If after 20 30 seconds the test taker cannot remember learning the list OR any of the items on the list then use the prompt i.e. the first one was 'tea' and then circle 'tea' or write a 'P' in parentheses after it to indicate that it was prompted and score as zero
- Use the prompt 'the first one was 'tea', only if the person cannot remember any of the grocery items
- Do not use any other prompts in this task (e.g. if the person says 'cooking oil' but cannot remember any of the other grocery items on the list do not use the 'tea' prompt or any other prompt)

#### Scoring:

The recall component of the memory item has a maximum score of 8 points.

- There are no part marks, the person scores either zero or 2 points for each item on the grocery list
- If 'tea' was used as a prompt then the maximum score the person can get on this task is 6/8
- mark as correct if the person says 'cooking oil' or ' oil'

Item	6 - Language	
Language Generativity – Anima	I Naming	
tell me the names of as many differe many different animals you can nam	te. In that one minute, I would like you to ont animals as you can. We'll see how e in one minute. (Repeat instructions if item is 8. If person names 8 new animals eed to continue.	
1	5	
2	6	
	7	
	7	
	8	

This item has a maximum score of 8 points.

- Time the test taker for one minute ONLY make sure that it is clear to the test taker when to start i.e. "When I say 'Go' you should start listing animals. Don't worry about me writing them down, say the animals as quickly as you can."
- If test taker does not speak English make sure that interpreter also understands the instructions and the importance of simultaneous interpreting.

#### Scoring:

If test taker says for example – 'big horse' and 'little horse', then record these as two separate animal names. Then at the end of the assessment, if the person is from an NESB country, check with the interpreter that these two names actually represent different concepts in the relevant language (e.g. in English – 'big horse' and 'little horse' are not separate animal names therefore an ESB person would score only one point (BUT, if the ESB person had said 'horse' and 'foal' then these are two separate concepts and the person would score two points). An NESB person depending on the language spoken may score two points if they used the correct two words for 'big horse' and 'little horse'. It is important here to distinguish between perseveration (i.e. repetition of the same animal name) and linguistic peculiarities of different languages which conceptualise/describe animals differently.

#### TOTAL SCORE

Add up the scores for each item to get a total score out of 30.

Any score of 22 or less should be considered as possible cognitive impairment and referred on for further investigation by the relevant physician.

# Global Physical Activity Questionnaire (GPAQ)

# **Analysis Guide**

Surveillance and Population-Based Prevention Prevention of Noncommunicable Diseases Department World Health Organization 20 Avenue Appia, 1211 Geneva 27, Switzerland For further information: www.who.int/chp/steps

# Global Physical Activity Questionnaire (GPAQ) Analysis Guide

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## 1 Overview

Introduction	<ul> <li>The Global Physical Activity Questionnaire was developed by WHO for physical activity surveillance in countries. It collects information on physical activity participation in three settings (or domains) as well as sedentary behaviour, comprising 16 questions (P1-P16). The domains are:</li> <li>Activity at work</li> <li>Travel to and from places</li> <li>Recreational activities</li> </ul>
Using GPAQ	<ul><li>Prior to using GPAQ, you should review the question by question section. This section, which follows the actual questions, will guide the interviewer in asking the questions and recording responses.</li><li>When using GPAQ, all the questions must be asked. Skips of questions do ONLY apply to the corresponding day and time variables if P1, P4, P7, P10, or P13 have been answered negatively. Skipping any other questions or removing any of the domains will restrict the results that you will be able to calculate.</li></ul>
Administration of the GPAQ	The GPAQ has been developed for face-to-face interviews conducted by trained interviewers. It had been tested in large scale population-based surveys with the general adult population.
Show cards	It is advised that show cards be used when the GPAQ is administered. Show cards should be developed for each of the activity types covered by the GPAQ: vigorous and moderate activity at work, transport activity, vigorous and moderate activity during leisure time, as well as sitting. Show cards will help the respondents to know what activities are meant by each question. They should be showing typical physical activities for the setting that the GPAQ is used in. Examples of generic show cards that will need to be adapted to the local context can be found on the GPAQ website: http://www.who.int/chp/steps/GPAQ/en/index.html
GPAQ version 1 and 2	This document provides information on version 2 of GPAQ. It is advised that you use version 2 of GPAQ. If you have already used GPAQ version 1 and need advise on analysing this information, please contact the STEPS team at <u>steps@who.int</u> .
Calculating and cleaning physical activity data	This document includes information on how to clean and analyse GPAQ data in general as well as specifically with the statistical package EpiInfo. The coding column of GPAQ is used as a reference for all the calculations. If you insert this questionnaire into another questionnaire, you should not change the coding column.

# **Overview**, Continued

Metabolic Equivalent (MET)	METs (Metabolic Equivalents) are commonly used to express the intensity of physical activities, and are also used for the analysis of GPAQ data.
	MET is the ratio of a person's working metabolic rate relative to the resting metabolic rate. One MET is defined as the energy cost of sitting quietly, and is equivalent to a caloric consumption of 1 kcal/kg/hour. For the analysis of GPAQ data, existing guidelines have been adopted: It is estimated that, compared to sitting quietly, a person's caloric consumption is four times as high when being moderately active, and eight times as high when being vigorously active.
	Therefore, when calculating a person's overall energy expenditure using GPAQ data, 4 METs get assigned to the time spent in moderate activities, and 8 METs to the time spent in vigorous activities.

# 2 The questionnaire

Physical Activity		
even if you do not consider yourself to be a physically active Think first about the time you spend doing work. Think of w household chores, harvesting food/crops, fishing or hunting following questions 'vigorous-intensity activities' are activitie	different types of physical activity in a typical week. Please answer the e person. ork as the things that you have to do such as paid or unpaid work, stuc for food, seeking employment. <i>[Insert other examples if needed]</i> . In ar s that require hard physical effort and cause large increases in breathin moderate physical effort and cause small increases in breathing or her	ly/training, nswering the ng or heart
Question	Response	Code
Work		
Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like <i>[carrying or lifting</i> <i>heavy loads, digging or construction work]</i> for at least 10 minutes continuously? <i>[INSERT EXAMPLES]</i> (USE SHOWCARD)	Yes 1 No 2 <i>If No, go to P 4</i>	P1
In a typical week, on how many days do you do vigorous- intensity activities as part of your work?	Number of days	P2
How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hours : minutes L : L hrs mins	P3 (a-b)
Does your work involve moderate-intensity activity, that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 If No, go to P 7	P4
In a typical week, on how many days do you do moderate- intensity activities as part of your work?	Number of days	P5
How much time do you spend doing moderate-intensity activities at work on a typical day?	Hours : minutes L : L hrs mins	P6 (a-b)
Travel to and from places		
The next questions exclude the physical activities at work th Now I would like to ask you about the usual way you travel t worship. [Insert other examples if needed]	at you have already mentioned. to and from places. For example to work, for shopping, to market, to pl	ace of
Do you walk or use a bicycle ( <i>pedal cycle</i> ) for at least 10 minutes continuously to get to and from places?	Yes 1 No 2 If No, go to P 10	P7
In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days	P8
How much time do you spend walking or bicycling for travel on a typical day?	Hours : minutes L : L hrs mins	P9 (a-b)

Continued on next page

# 2 The questionnaire, Continued

Question	Response	Code
Recreational activities		
The next questions exclude the work and transport activities that Now I would like to ask you about sports, fitness and recreationa		
Do you do any vigorous-intensity sports, fitness or recreational ( <i>leisure</i> ) activities that cause large increases in breathing or heart rate like [ <i>running or football</i> ] for at least 10 minutes continuously?	Yes 1	P10
[INSERT EXAMPLES] (USE SHOWCARD)	No 2 If No, go to P 13	
In a typical week, on how many days do you do vigorous- intensity sports, fitness or recreational ( <i>leisure</i> ) activities?	Number of days	P11
How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?	Hours : minutes hrs mins	P12 (a-b)
Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate such as brisk walking, [cycling, swimming, volleyball] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 <i>If No, go to P16</i>	P13
In a typical week, on how many days do you do moderate- intensity sports, fitness or recreational ( <i>leisure</i> ) activities?	Number of days	P14
How much time do you spend doing moderate-intensity sports, fitness or recreational ( <i>leisure</i> ) activities on a typical day?	Hours : minutes Hours : minutes	P15 (a-b)
Sedentary behaviour		
The following question is about sitting or reclining at work, at hou desk, sitting with friends, traveling in car, bus, train, reading, play INSERT EXAMPLES] (USE SHOWCARD)		
How much time do you usually spend sitting or reclining on a ypical day?	Hours : minutes	P16 (a-b)

# **3 GPAQ Question by Question Guide**

Physical Activity		
Next I am going to ask you about the time you spend doing different to even if you do not consider yourself to be a physically active person. Think first about the time you spend doing work. Think of work as the household chores, harvesting food/crops, fishing or hunting for food, s following questions 'vigorous-intensity activities' are activities that require rate, 'moderate-intensity activities' are activities that require moderate Read this opening statement out loud. It should not be omitted. The respond unpaid work, household chores, harvesting food, fishing or hunting for food, s he/she travels from place to place, and finally about the time spent in vigorou Remind the respondent when he/she answers the following questions that 'vig large increases in breathing or heart rate, 'moderate-intensity activities' are and breathing or heart rate. Don't forget to use the showcard which will help the r	things that you have to do such as paid or unpaid work, stud seeking employment. [Insert other examples if needed]. In a uire hard physical effort and cause large increases in breathing physical effort and cause small increases in breathing or he lent will have to think first about the time he/she spends doing work eeking employment [Insert other examples if needed]), then about it s as well as moderate physical activity during leisure time. gorous-intensity activities' are activities that require hard physical effort trivities that require moderate physical effort and cause small increases.	dy/training, nswering the ng or heart art rate. (paid or the time ffort and cause ases in
Question	Response	Code
Work		
Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1	P1
Ask the participant to think about vigorous-intensity activities at work only. Activities are regarded as vigorous intensity if they cause large increases in breathing and/or heart rate.	No 2 If No, go to P 4	
In a typical week, on how many days do you do vigorous-intensity activities as part of your work? "Typical week" means a week when the participant is engaged in his/her usual activities. Valid responses range from 1-7.	Number of days	P2
How much time do you spend doing vigorous-intensity activities at work on a typical day? Ask the participant to think of a typical day he/she can recall easily in which he/she engaged in vigorous-intensity activities at work. The participant should only consider those activities undertaken continuously for 10 minutes or more. Probe very high responses (over 4 hrs) to verify.	Hours : minutes	P3 (a-b)
Does your work involve moderate-intensity activity, that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD) Ask the participant to think about moderate-intensity activities at work only.	Yes 1 No 2 If No, go to P 7	P4
Activities are regarded as moderate intensity if they cause small increases in breathing and/or heart rate.		
In a typical week, on how many days do you do moderate-intensity activities as part of your work? "Typical week" means a week when the participant is engaged in his/her usual activities. Valid responses range from 1-7.	Number of days	P5
How much time do you spend doing moderate-intensity activities at work on a typical day? Ask the participant to think of a typical day he/she can recall easily in which he/she engaged in moderate-intensity activities at work. The participant should only consider those activities undertaken continuously for 10 minutes or more. Probe very high responses (over 4 hrs) to verify.	Hours : minutes L : L hrs mins	P6 (a-b)

## 3 GPAQ Question by Question Guide, Continued

Physical Activity, Continued		
Question	Response	Code
Travel to and from places		
The next questions exclude the physical activities at work that you hav Now I would like to ask you about the usual way you travel to and from worship. [Insert other examples if needed] The introductory statement to the following questions on transport-related phy about how they travel around getting from place-to-place. This statement show	n places. For example to work, for shopping, to market, to p rsical activity is very important. It asks and helps the participant to r	
Do you walk or use a bicycle ( <i>pedal cycle</i> ) for at least 10 minutes continuously to get to and from places?	Yes 1	P7
Select the appropriate response.	No 2 If No, go to P 10	
How much time do you spend walking or bicycling for travel on a typical day? Ask the participant to think of a typical day he/she can recall easily in which	Hours : minutes	P9
he/she engaged in transport-related activities. The participant should only consider those activities undertaken continuously for 10 minutes or more. Probe very high responses (over 4 hrs) to verify.		(a-b)
Recreational activities		
The next questions exclude the work and transport activities that you Now I would like to ask you about sports, fitness and recreational activ This introductory statement directs the participant to think about recreational a and exercise but is not limited to participation in competitions. Activities report only recreational activities and not to include any activities already mentioned	vities (leisure) [Insert relevant terms]. activities. This can also be called discretionary or leisure time. It in ted should be done regularly and not just occasionally. It is importa	
Do you do any vigorous-intensity sports, fitness or recreational ( <i>leisure</i> ) activities that cause large increases in breathing or heart rate like [ <i>running</i> or football] for at least 10 minutes continuously?	Yes 1	
[INSERT EXAMPLES] (USE SHOWCARD)		P10
Ask the participant to think about recreational vigorous-intensity activities only. Activities are regarded as vigorous intensity if they cause large increases in breathing and/or heart rate.	No 2 If No, go to P 13	
In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational <i>(leisure)</i> activities?	Number of days	P11
"Typical week" means a week when the participant is engaged in his/her usual activities. Valid responses range from 1-7.		
How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?		D40
Ask the participant to think of a typical day he/she can recall easily in which he/she engaged in recreational vigorous-intensity activities. The participant should only consider those activities undertaken continuously for 10 minutes or more. Probe very high responses (over 4 hrs) to verify.	Hours : minutes	P12 (a-b)
Do you do any moderate-intensity sports, fitness or recreational ( <i>leisure</i> ) activities that cause a small increase in breathing or heart rate such as brisk walking, [cycling, swimming, volleyball] for at least 10 minutes continuously?	Yes 1	540
[INSERT EXAMPLES] (USE SHOWCARD)		P13
Ask the participant to think about recreational moderate-intensity activities only. Activities are regarded as moderate intensity if they cause small increases in breathing and/or heart rate.	No 2 If No, go to P16	
In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational <i>(leisure)</i> activities? <i>"Typical week" means a week when the participant is engaged in his/her</i>	Number of days	P14
usual activities. Valid responses range from 1-7.		

# 3 GPAQ Question by Question Guide, Continued

Physical Activity, Continued					
Question	Question Response				
How much time do you spend doing moderate-intensity sports, fitness or recreational ( <i>leisure</i> ) activities on a typical day?		Dic			
Ask the participant to think of a typical day he/she can recall easily in which he/she engaged in recreational moderate-intensity activities. The participant should only consider those activities undertaken continuously for 10 minutes or more. Probe very high responses (over 4 hrs) to verify.	Hours : minutes	P15 (a-b)			
Sedentary behaviour					
The following question is about sitting or reclining at work, at home, g desk, sitting with friends, traveling in car, bus, train, reading, playing o [INSERT EXAMPLES] (USE SHOWCARD)					
How much time do you usually spend sitting or reclining on a typical day? Ask the participant to consider total time spent sitting at work, in an office, reading, watching television, using a computer, doing hand craft like knitting, resting etc. The participant should not include time spent sleeping.	Hours : minutes	P16 (a-b)			

### 4 Cleaning GPAQ data

Introduction	It is important to standardize the way in which the data collected are cleaned and analysed. Please use the guidelines below when cleaning and analysing your data. The cleaning and analysis guidelines use the coding column in the questionnaire as an identifier.
Cleaning	You should clean all domains as a combined set. While some of the calculations of results use all the domains and others use only one of the domains, it is necessary that each respondent has an overall "clean" response

domains, it is necessary that each respondent has an overall "clean" response to all physical activity questions. To be included in the analyses, each participant must have a valid response for at least one domain and have no invalid responses for any domains.

Check for the following for all the domains.

If	Then
Values in the hours column are 15,	move them into the corresponding
30, 45, or 60	minutes variable, if the
	corresponding minutes variable is
	empty or zero (most likely a data
	recording error).
Maximum values: If for at least one	remove the case from all analyses.
"sub-domain" (vigorous work,	
moderate work, transport, vigorous	
recreation, or moderate recreation	
activity) the value of hours+minutes	
>16 hours	
If a respondent reports implausible	remove the case from all analyses.
values (eg., >7 days in any days	
column)	
If a respondent has inconsistent	remove the case from all analyses.
answers (eg., 0 days, but values >0	
in the corresponding time variables)	
If one whole "sub-domain"	include the case in the analysis,
(vigorous work, moderate work,	assuming no activity (0 days, 0 time)
transport, vigorous recreation,	for this "sub-domain". That means
or moderate recreation activity)	that, as long as at least one "sub-
has missing values, but the other	domain" has valid answers, and all
"sub-domains" are valid	others are missing, this person will
	be included in analyses.

#### Notes

Overall, this cleaning method should result in the same denominator across all domains and all analyses.

For information on how to create P3, P6, P9, P12, and P15 see the Cleaning GPAQ with EpiInfo section at the end of this document (p. 12).

### 4 Cleaning GPAQ data, Continued

Detailed<br/>cleaning<br/>instructionsThere are detailed cleaning instructions on how to clean each variable in the<br/>Cleaning GPAQ with EpiInfo section of this document (p. 11). This section<br/>includes details on how to clean the variables and the associated EpiInfo<br/>code.

### 5 Cleaning GPAQ data with EpiInfo

Introduction GPAQ collects information on three domains. These domains are:

- Activity at work
- Travel to and from places
- Recreational activities.

For analysis purposes these domains can be further broken down into six different "sub-domains". These "sub-domains" are:

- Vigorous work (codes P1-P3)
- Moderate work (codes P4-P6)
- Travel (codes P7-P9)
- Vigorous recreation (codes P10-P12)
- Moderate recreation (codes P13-P15)
- Sitting (code P16)

Grouping<br/>the<br/>GPAQ<br/>sectionsThe GPAQ data are cleaned as a whole. Thus is a participant gave an invalid answer<br/>to any domain, then their entire response is not included in any analyses. However,<br/>a participant needs only to give a valid response to a minimum of one domain,<br/>leaving the remaining domains blank, to be included in the analyses.

Cleaning A "CleanRecode" program exists for each subset of physical activity questions. Programs These are: CleanRecode P1-P3, CleanRecode P4-P6, CleanRecode P7-P9, CleanRecode P10-P12, CleanRecode P13-P15, and CleanRecode P16. The first 5 of these programs are identical with the only exception being that the question codes are changed.

All programs can be downloaded from <u>http://www.who.int/chp/steps/resources/database/en/index.html</u> by clicking on "EpiInfo Analysis Programs".

CleanRecode P1-P3 is described in the following table. This same description applies to CleanRecode P4-P6, CleanRecode P7-P9, CleanRecode P10-P12, and CleanRecode P13-P15. Since the program CleanRecode P16 differs from the other 5 CleanRecode programs, its description is provided in the second table below.

## 5 Cleaning GPAQ data with EpiInfo, Continued

CleanRecode P1-	·P3							
Questions Used	P1, P2, P3a	, P3b						
General Information	Before checking for valid responses to P1 through P3a&b, P3a and P3b are checked for possible data entry errors (i.e. minutes entered where hours are expected). To have a "clean" response, respondents must have answered all 3 questions correctly and consistently (P1t3CLN=1).							
Modified Variables	Before any tests. To su 15, 30, 45,	new variables are created, P3a and P3b a immarize, these tests try to correct obvio or 60 were entered as hour values in P3a lataset used for analysis, the actual datas	are modified ous data entry . These chan	using the follow errors where miges are only sav	ing logical inute values of			
	Condition	and set used for analysis, the detail datas		New P3a Value	New P3b Value			
	P3a=15 AN P3b=88 OR	D (P3b=(.) OR P3b=0 OR P3b=15 OR I P3b=99)	P3b=77 OR	0	15			
	P3a=30 AN P3b=88 OR	D (P3b=(.) OR P3b=0 OR P3b=30 OR I P3b=99)	P3b=77 OR	0	30			
	P3b=88 OR			0	45			
	P3b=88 OR	,		1	0			
	AND P3b=		OR (P3a=9	0	0			
		P3a=88 OR P3a=99		0	(leave as is)			
Carrente d		P3b=88 OR P3b=99	<b>X7 - 1</b>	(leave as is) Condition	0			
Created Variables	Name P3amin	Purpose Computes min value for P3a.	Value 0	P3a=(.)				
variables	1 Jannii	Computes min value for 1 5a.	P3a*60	ELSE				
	P3bmin	Set equal to P3b, with 0's replacing	0	P3b=(.)				
	1 501111	missing values.		ELSE				
	P3	Total time in mins.	P3b P3amin+P 3bmin					
	P2CLN	Checks for a valid response to P2	1	P1=1 AND P2>0 AND P2<8 OR P1=2 AND (P2=0 OR P2=(.) OR P2=99)				
	P3CLN	Chastra for a valid rear and to D2: D2	2	ELSE				
	POCLIN	must have a valid response with nr. of days = 1 through 7, and P3 mustP2<8 AND P3>9 AP3<961						
		be at least 10 mins. and at most 960 mins. (max. of 16 hrs. per day)		OR P2CLN=1 AN P2=(.) OR P2= P3=0				
			2	ELSE				
	P1t3CLN	Checks for valid response to P1 through P3a&b. Allows for respondents to skip entire section but a check in the physical activity programs that use these cleaning	1	P3CLN=1 AN OR P1=(.) AND ( P2=(.) OR P2= P3=0 AND V3	P2=0 OR =99) AND			
		programs ensures that <u>at least one</u> <u>section</u> of all physical activity sections has a response.	2	ELSE				

# 5 Cleaning GPAQ data with EpiInfo, Continued

CleanRecode	P16							
Questions Used	P16a, P16b							
General Information	Responses are first checked for possible data entry errors (i.e. minutes entered where hours are expected). To have a "clean" response, respondents must have given a valid							
mormution	response to P16 (P16CLN=1).							
Modified		y new variables are created,	P16a and P16b are me	odified using th	ne following			
Variables		ts. To summarize, these tes						
		lues of 15, 30, 45, or 60 we						
		aved to the temporary datase	et used for analysis, th	e actual datase	t is left			
	unchanged Condition			New P16a	New P16b			
	Condition	1		Value	Value			
		AND (P16b=(.) OR P16b=0	OR P16b=15 OR	0	15			
		OR P16b=88 OR P16b=99)						
		AND (P16b=(.) OR P16b=0 OR P16b=88 OR P16b=99)	0	30				
		AND (P16b=(.) OR P16b=0	0	45				
		OR P16b=88 OR P16b=99)	0K1100-15 0K	0	15			
		AND (P16b=(.) OR P16b=0	1	0				
		OR P16b=88 OR P16b=99)						
		AND P16b=77) OR (P16a=8	0	0				
		AND P16b=99)	0					
		OR P16a=88 OR P16a=99 OR P16b=88 OR P16b=99	0	(leave as is)				
Created	Name	Purpose	Value	(leave as is) Condition	0			
Variables	P16amin	Computes min value for	0	P16a=(.)				
( unubics	1 Toumin	P16a	P16a*60	ELSE				
	P16bmin							
		0's replacing missing	P16b	ELSE				
		values						
	P16	Total time in mins	P16amin+P16bmin					
	P16CLN	Checks for a valid	1	P16<1441 A	ND Valid=1			
		response to P16 (can be from 0 mins, to 1440	2	ELSE				
		mins. (24 hrs.))						
		mms. (27 ms.))	1					

### 6 Analysis Guidelines and Calculations

Introduction	A population's physical activity (or inactivity) can be described in different ways.
	The two most common ways are

- (1) to estimate a population's mean or median physical activity using a continuous indicator such as MET-minutes per week or time spent in physical activity, and
- (2) to classify a certain percentage of a population as 'inactive' or 'insufficiently active' by setting up a cut-point for a specific amount of physical activity.

The following guidelines describe both how to derive at continuous as well as categorical indicators when analysing GPAQ data.

**Continuous** As described in the overview (p. 3), MET values are applied to the time variables according to the intensity (moderate or vigorous) of the activity. Applying MET values to activity levels allows us to calculate total physical activity.

For the calculation of a person's overall energy expenditure using GPAQ data, the following MET values are used:

Domain	MET value
Work	• Moderate MET value = 4.0
	• Vigorous MET value = 8.0
Transport	Cycling and walking MET value = 4.0
Recreation	• Moderate MET value = 4.0
	• Vigorous MET value = 8.0

 WHO recommenddations on physical activity for health
 For the calculation of a categorical indicator, the total time spent in physical activity during a typical week and the intensity of the physical activity are taken into account.
 Throughout a week, including activity for work, during transport and leisure time, adults should do at least

- 150 minutes of moderate-intensity physical activity OR
- 75 minutes of vigorous-intensity physical activity OR
- An equivalent combination of moderate- and vigorous-intensity physical activity achieving at least 600 MET-minutes.

## 6 Analysis Guidelines and Calculations, Continued

Not meeting WHO	Description: Percentage of respondents not meeting WHO recommendations on physical activity for health (respondents doing less than 150 minutes of moderate-intensity physical activity per week, or equivalent).
recommen-	
dations on physical	Instrument questions: • P1-P6a&b: activity at work
activity for	• <b>P7-P9a&amp;b:</b> travel to and from places
health	• <b>P10 D150 8-b</b> , respectively estivities

• P10-P15a&b:	recreational	activities
---------------	--------------	------------

	Not meeting WHO recommendations on physical activity for health								
A rea Men				Women		Both Sexes			
Age Group (years)	n	% not meeting recs	95% CI	n	% not meeting recs	95% CI	n	% not meeting recs	95% CI

Questions	P1-P15a&b								
-	11-11Jaco								
Used									
Program	0	cs (unweighted), PnotmeetingrecsWT (weighted)							
Equations	Total physical activity MET-minutes/week (= the sum of the total MET minutes								
	of activity comp	buted for each setting)							
	Equation: Total	Physical Activity MET-minutes/week = $[(P2 * P3 * 8) + (P5 * P3 * 8)]$							
	P6 * 4) + (P8 * 1)	P9 * 4) + (P11 * P12 * 8) + (P14 * P15 * 4)]							
	WHO         Physical activity cutoff value								
	recommen-	recommen-							
	dations								
	Not meeting	• IF: Total Physical Activity MET minutes per week is < 600							
	recommen-								
	dations								
Program	Reports percenta	age of respondents who do not meet WHO recommendations on							
Information	physical activity	for health. Before any of the below variables are created ALL							
	CleanRecode pr	CleanRecode programs are called. To be included in the output, the respondent							
	1	must have either left blank or given a valid response to each subset of the							
		questions AND have given a valid response to at least one							
	1 2 2	ysical activity questions (CLN=1).							
	<u>subset</u> of the pli								

Created Variables	Name	Purpose	Values	Condition
	P1t3	MET value of	P2*P3*8	P1t3CLN=1
		vigorous work activity per week	(.)	ELSE
	P4t6	MET value of	P5*P6*4	P4t6CLN=1
		moderate work activity per week	(.)	ELSE
	P7t9	MET value of	P8*P9*4	P7t9CLN=1
		transport activity per week	(.)	ELSE
	P10t12	MET value of vigorous recreational activity per week	P11*P12*8	P10t12CLN=1
		activity per week	(.)	ELSE
	P13t15	MET value of	P14*P15*4	P13t15CLN=1
		moderate recreational activity per week	(.)	ELSE
	Ptotal	Sum of all activity per week	p1t3+p4t6+p7t9+p10t 12+p13t15	
	CLN	Checks to see if all physical activity responses, as a combined set, are valid: all subsets of responses must be clean and at least one subset of responses	1	Valid=1 AND P1t3CLN=1 AND P4t6CLN=1 AND P7t9CLN=1 AND P10t12CLN=1 AND P13t15CLN=1 <b>AND</b> P1 $\neq$ (.) OR P4 $\neq$ (.) OR P7 $\neq$ (.) OR P10 $\neq$ (.) OR P13 $\neq$ (.)
		must have a response (not missing)	2	ELSE
	С	Output table values	"Does not meet recommendations"	Ptotal<600
			"Meets recommendations"	Ptotal≥600

Description: Mean / median time of total physical activity on average per day. Total physical

activity

- Instrument questions
- **P1-P6a&b:** activity at work
- **P7-P9&b:** travel to and from places
- P10-P15a&b: recreational activities

	Mean/Median minutes of total physical activity on average per day								
Age		Men			Women	l		Both Sex	es
Group (years)	n	# minutes	95% CI	n	# minutes	95% CI	n	# minutes	95% CI

Questions	P1-P15a&	żb								
Used										
Program	Ptotal (un	nweighted mean & me	edian values), <b>H</b>	PtotalWT (weighted mean						
0		PtotalmedianWT (we								
Program	Reports th	he mean or median an	nount of physic	al activity per day in minutes.						
Information				ALL CleanRecode programs are						
				ondent must have either left blank						
		or given a valid response to each subset of the physical activity questions AND								
	have give	have given a valid response to at least one subset of the physical activity								
	questions	(CLN=1).								
Created	Name	Purpose	Values	Condition						
Variables	P1t3	Vigorous work	P2*P3	P1t3CLN=1						
		activity in minutes	(.)	ELSE						
		per week								
	P4t6	Moderate work	P5*P6	P4t6CLN=1						
		activity in minutes	(.)	ELSE						
		per week								
	P7t9	Transport activity in	P8*P9	P7t9CLN=1						
	<b>D10.10</b>	minutes per week	(.)	ELSE						
	P10t12	Vigorous	P11*P12	P10t12CLN=1						
		recreational activity in minutes per week	(.)	ELSE						
	P13t15	Moderate	P14*P15	P13t15CLN=1						
	1 15(15	recreational activity	(.)	ELSE						
		in minutes per week	(.)	LLOL						
	Ptotalday	Sum of all activity	(p1t3+p4t6+							
		per week divided by	p7t9+p10t12							
		7 to get avg. per day	+p13t15)/7							
	CLN	Checks to see if all	1	Valid=1 AND P1t3CLN=1 AND						
		physical activity		P4t6CLN=1 AND P7t9CLN=1						
		responses, as a		AND P10t12CLN=1 AND						
		combined set, are		P13t15CLN=1						
		valid: all subsets of		AND						
		responses must be clean and at least		$P1\neq(.) \text{ OR } P4\neq(.) \text{ OR } P7\neq(.) \text{ OR}$						
		one subset of	2	P10≠(.) OR P13≠(.) ELSE						
		responses must have	2	ELSE						
		a response (not								
		missing)								
	1	11100111 <u>6</u> )	1	1						

Setting-<br/>specificDescription: Mean / median number of minutes spent on average per day, in work-,<br/>transport- and recreation-related physical activity.

specific physical activitymean / median

Instrument questions

- **P1-P6a&b:** activity at work
- **P7-P9&b:** travel to and from places
- P10-P15a&b: recreational activities

	Mean/Median minutes of [insert domain]-related physical activity on average per day								
Age		Men			Women	L		Both Sex	es
Group (years)	n	# minutes	95% CI	n	# minutes	95% CI	n	# minutes	95% CI

Questions	P1-P15a8	żh								
Used	1111040									
Program	Psetsneci	fic (unweighted mean &	median values) <b>F</b>	SetspecificWT (weighted						
1 logram	<b>Psetspecific</b> (unweighted mean & median values), <b>PsetspecificWT</b> (weighted mean values), <b>PsetspecificmedianWT</b> (weighted median values)									
Program				vity in minutes. Before any						
Information				e programs are called. To						
mormation										
		be included in the output, the respondent must have either left blank or given a								
		valid response to each subset of the physical activity questions AND have given a valid response to <u>at least one subset</u> of the physical activity questions								
			bset of the physica	I activity questions						
~ -	(CLN=1).		[	~ ~ ~						
Created	Name	Purpose	Values	Condition						
Variables	P1t3	Vigorous work activity	P2*P3	P1t3CLN=1						
		in minutes per week	(.)	ELSE						
	P4t6	Moderate work activity	P5*P6	P4t6CLN=1						
		in minutes per week	(.)	ELSE						
	P7t9	Transport activity in	P8*P9	P7t9CLN=1						
		minutes per week	(.)	ELSE						
	P10t12	Vigorous recreational	P11*P12	P10t12CLN=1						
		activity in minutes per	(.)	ELSE						
		week								
	P13t15	Moderate recreational	P14*P15	P13t15CLN=1						
		activity in minutes per week	(.)	ELSE						
	Pwork-	Average work-related	(p1t3+p4t6)/7							
	day	activity per day								
	Ptravel-	Average transport-	p7t9/7							
	day	related activity per day								
	Precday	Average recreation-	(p10t12+p13t15)							
		related activity per day	/7							
	CLN	Checks to see if all	1	Valid=1 AND P1t3CLN=1						
		physical activity		AND P4t6CLN=1 AND						
		responses, as a		P7t9CLN=1 AND						
		combined set, are valid:		P10t12CLN=1 AND						
		all subsets of responses		P13t15CLN=1						
		must be clean and at		AND						
		least one subset of		$P1 \neq (.) \text{ OR } P4 \neq (.) \text{ OR } P7 \neq (.)$						
		responses must have a		OR P10≠(.) OR P13≠(.)						
		response (not missing)	2	ELSE						

**No** Description: Percentage of respondents classified as doing no work-, transport-, or recreation-related physical activity.

activity by setting

Instrument questions

- **P1-P6a&b:** activity at work
- **P7-P9&b:** travel to and from places
- P10-P15a&b: recreational activities

	No [insert domain]-related physical activity									
Age Group	roup Men				Women			Both Sexes		
(years)	n	%	95% CI	n	%	95% CI	n	%	95% CI	

Questions	P1-P15	a&b						
Used								
Program	Pnoact	ivitybyset (unweighte	d), <b>Pnoactivi</b>	tybysetWT (weighted)				
Program Information	recreati created the resp subset of	Reports the percentage of respondents who reported no work-, transport-, or ecreation-related physical activity. Before any of the below variables are reated ALL CleanRecode programs are called. To be included in the output, he respondent must have either left blank or given a valid response to each ubset of the physical activity questions AND have given a valid response to <u>at</u> <u>east one subset</u> of the physical activity questions (CLN=1).						
Created		Name         Purpose         Values         Condition						
Variables			"did work activity" "did no work activity"	P1=1 OR P4=1 ELSE				
	Trans	Indicates whether or not respondent did any transport-related activity	"did transport activity" "did no transport activity"	P7=1 ELSE				
	Rec	Indicates whether or not respondent did any recreation- related activity	"did recreation activity" "did no recreation activity"	P10=1 OR P13=1 ELSE				
	CLN	Checks to see if all physical activity responses, as a combined set, are valid: all subsets of responses must be clean and at least one subset of responses must have a response (not missing)	2	Valid=1 AND P1t3CLN=1 AND P4t6CLN=1 AND P7t9CLN=1 AND P10t12CLN=1 AND P13t15CLN=1 <b>AND</b> P1 $\neq$ (.) OR P4 $\neq$ (.) OR P7 $\neq$ (.) OR P10 $\neq$ (.) OR P13 $\neq$ (.) ELSE				

**Composition** Description: Percentage of total physical activity on average per day that comes from each of the 3 types of activity: work-, transport-, or recreation-related. of total physical Instrument questions activity

- **P1-P6a&b:** activity at work
- **P7-P9&b:** travel to and from places
- P10-P15a&b: recreational activities

Composition of total physical activity									
Age Group —				Gender					
(years)	n	% Work	95% CI	% Transport	95% CI	% Recreation	95% CI		

Qu. Used	P1-P15a	&b							
Program		sition (unweighted), Pcompos	itionWT (weighted	d)					
Program Infor- mation	Reports activity created	the percentage of activity that c (work, transport, or recreation). ALL CleanRecode programs ar ent must have either left blank of	comes from each of Before any of the e called. To be inc	f the three types of below variables are luded in the output, the					
	the physical activity questions AND have given a valid response to <u>at least one</u> <u>subset</u> of the physical activity questions (CLN=1).								
Created	Name	Purpose	Values	Condition					
Variables	P1t3 Vigorous work activity in minutes per week		P2*P3 (.)	P1t3CLN=1 ELSE					
	P4t6	Moderate work activity in	P5*P6	P4t6CLN=1					
		minutes per week	(.)	ELSE					
	P7t9	Transport activity in minutes	P8*P9	P7t9CLN=1					
	per week		(.)	ELSE					
	P10t12 Vigorous recreational activity in minutes per week		P11*P12	P10t12CLN=1					
			(.)	ELSE					
	P13t15	Moderate recreational activity in minutes per week	P14*P15	P13t15CLN=1					
		-	(.)	ELSE					
	Ptotal	Sum of all activity per week	p1t3+p4t6+p7t9+ p10t12+p13t15						
	Percent- Work	Percent of all activity from work-related activities	(p1t3+p4t6)/Ptota 1*100						
	Percent- Trans	Percent of all activity from transportation-related activities	p7t9/Ptotal*100						
	Percent- Rec	Percent of all activity from recreational activities	(p10t12+p13t15)/ Ptotal*100						
	CLN	Checks to see if all physical activity responses, as a combined set, are valid: all subsets of responses must be clean and at least one subset of responses must have a response (not missing)	1	Valid=1 AND P1t3CLN=1 AND P4t6CLN=1 AND P7t9CLN=1 AND P10t12CLN=1 AND P13t15CLN=1 <b>AND</b> P1 $\neq$ (.) OR P4 $\neq$ (.) OR P7 $\neq$ (.) OR P10 $\neq$ (.) OR P13 $\neq$ (.)					
			2	ELSE					

### No Description: Percentage of respondents not engaging in vigorous physical activity.

vigorous physical activity

- cal Instrument questions
  - **P1-P6a&b:** activity at work
  - **P7-P9&b:** travel to and from places
  - P10-P15a&b: recreational activities

No vigorous physical activity										
Age Group	Men				Women			Both Sexes		
(years)	n % 95% CI		n	%	95% CI	n	%	95% CI		

Qu. Used	P1-P15	a&b								
Program	Pnovig	orous (unweighted), l	PnovigorousWT	(weighted values)						
Program	Reports	s percentage of respon	dents who did no	vigorous physical activity. Before						
Infor-	any of	the below variables ar	e created ALL Clo	eanRecode programs are called.						
mation	To be i	ncluded in the output,	the respondent m	ust have either left blank or given						
	a valid	a valid response to each subset of the physical activity questions AND have								
	given a valid response to <u>at least one subset</u> of the physical activity questions (CLN=1).									
Created	Name									
Variables	С	Output table values	"did vigorous physical activity"	P1=1 OR P10=1						
			"did no vigorous physical activity"	ELSE						
	CLN	Checks to see if all physical activity responses, as a combined set, are valid: all subsets of responses must be clean and at least one subset of responses must have a response (not missing)	1	Valid=1 AND P1t3CLN=1 AND P4t6CLN=1 AND P7t9CLN=1 AND P10t12CLN=1 AND P13t15CLN=1 AND P1 $\neq$ (.) OR P4 $\neq$ (.) OR P7 $\neq$ (.) OR P10 $\neq$ (.) OR P13 $\neq$ (.) ELSE						

Sedentary Description: Minutes spent in sedentary activities on average per day.

- Instrument questions
- P16: sedentary behaviour

Mean/Median minutes spent in sedentary activities on average per day									
Age	Men			Women			Both Sexes		
Group (years)	n	# minutes	95% CI	n	# minutes	95% CI	n	# minutes	95% CI

Questions Used	P16a&b							
Program	Psedentary (unweighted mean & median values), PsedentaryWT							
	(weighted mean values), <b>PsedentarymedianWT</b> (weighted median values)							
Program	Reports the mean or median amount of sedentary activity in minutes.							
Information	Before any of the below variables are created ALL CleanRecode programs							
	are called. To be included in the output, the respondent must have either							
	left blank or given a valid response to each subset of the physical activity							
	questions AND have given a valid response to at least one subset of the							
	physical activity questions (CLN=1). Note: P16 was created in							
	CleanRecodeP16 from P16a and P16b. It contains the total sedentary time							
	in mins.							
Created	Name	Purpose	Values	Condition				
Variables	CLN	Checks to see if all	1	Valid=1 AND P16CLN=1				
		physical activity						
		responses, as a						
		combined set, are						
		valid: all subsets of						
		responses must be clean and at least						
		one subset of	2	ELSE				
		responses must have	2	LLSL				
		a response (not						
		missing)						

#### CONSENT FORM FOR SENSORY EVALUATION

# STUDY TITLE: Impact evaluation of pumpkin seeds on glycaemic and lipemic responses of type 2 diabetic old age population of urban Vadodara.

#### PhD Guide

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#### **Purpose of the study**

Diabetes mellitus is one the major non-communicable diseases. It is the most prevalent metabolic condition and one of the major health problems worldwide. Diabetes mellitus is a growing problem worldwide because of long life expectancy and life style modifications. Diabetes mellitus complications and comorbidities are more frequent in elders compare to young group. One of the pharmacological ways to control blood sugar level is use of botanical products or functional foods. Pumpkin seeds have the potential to reduce glycaemic response. Decreasing the glycaemic index of the diet may improve insulin sensitivity, reducing the risk of diseases. This study has been planned to determine the glycemic index of pumpkin seed incorporated recipes.

#### PROTOCOL OF THE STUDY

If you decide to join this study, information regarding medical history, family history of lifestyle diseases will be assessed with the help of questionnaire. There will be approximately four visits lasting approximately 130 minutes in each visit. On two of the study visits you will be asked to consume 50 gm of glucose as reference food. On other two visits, you will be asked to consume standard recipe (Without pumpkin seeds) or the test recipe (With pumpkin seeds). Both of them will contain 50gm of carbohydrates and will be tested on separate days. Each study visit will include following procedures:

- You should not drink or eat any food substance before 12 hours of the study visit.
- Avoid any vigorous exercise in the morning of a visit.
- Provide fasting blood sample taken by finger prick.
- Consume specified portion of reference or test food within 15 minutes.
- Provide finger prick blood sample at 15, 30,45,60,90 and 120 minutes after beginning to eat the food.

#### Costs:

This study only requires your time and cooperation. All the cost will be borne by the researcher and there is no financial compensation for the participation in this study.

#### POSSIBLE BENEFITS AND RISK

This study will help to increase scientific knowledge about glycaemic index of pumpkin seed incorporated recipes. The risk of participation is minimal as we will use disposable needles, lancets and syringes for withdrawing blood and it will be done by trained technician.

#### Confidentiality

Your identity in this study will be treated as confidential. Your personal information will not be shared to anyone but your results will may be published for the scientific purpose.

#### Right to withdraw

Your decision to join this study is voluntary. You may quit at any time without notice. We hope you will take part in this study for entire period because we need all the information for conclusions.

#### **Voluntary Consent**

Your decision to join in this study is voluntary. You may quit at any time for any reason without notice. If you have any questions about any part of there study, you have right to ask PhD student or guide to collect information before you sign this consent form. You should not join any other studies where you would assign to receive any medication, special test or any treatment.

Investigator's statement

I have explained the research programme, purpose of the study and possible benefits and risks of participating in the study. The participant was given an opportunity to discuss the procedures and any other queries.

Signature of the investigator with date

#### **Participant's Statement**

I have clarified that I have read, or had read to me and I understand the description of the study. I voluntarily consent to join in this study.

Signature\_\_\_\_\_

Date\_\_\_\_\_

Name\_\_\_\_\_

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#### CONSENT FORM FOR SENSORY EVALUATION

# **STUDY TITLE**: Impact evaluation of pumpkin seeds on glycaemic and lipemic responses of type 2 diabetic old age population of urban Vadodara.

PhD Guide Prof.Komal Chauhan Department of Foods and Nutrition, Faculty of Family and Community Sciences, The M S University of Baroda, Vadodara (M): 9898790340 **PhD Student** Ms.Nikita Joshi Department of Foods and Nutrition, Faculty of Family and Community sciences, The M S University of Baroda, Vadodara (M):8511220869

#### **Purpose of the study**

Diabetes mellitus is one the major non-communicable diseases. It is the most prevalent metabolic condition and one of the major health problems worldwide. Diabetes mellitus is a growing problem worldwide because of long life expectancy and life style modifications. Diabetes mellitus complications and comorbidities are more frequent in elders compare to young group. One of the pharmacological ways to control blood sugar level is use of botanical products or functional foods. This study has been planned to determine the acceptability of pumpkin seed incorporated recipes.

#### PROTOCOL OF THE STUDY

If you give your consent to join this study, you will be asked to taste pumpkin seed incorporated recipes and carry out the sensory evaluation of the recipes using the hedonic rating scale and composite scoring scale. 7 recipes will be developed by using pumpkin seeds. Sensory evaluation will be carried out on 7 different days.

#### COSTS

This study only requires your time and cooperation. All the cost will be borne by the researcher and there is no financial compensation for the participation in this study.

#### POSSIBLE BENEFITS AND RISK

This study will help to increase scientific knowledge about the taste and overall acceptability of pumpkin seed incorporated recipes. The risk of participation in this study is minimal.

#### Confidentiality

Your identity in this study will be treated as confidential. Your personal information will not be shared to anyone but your results will may be published for the scientific purpose.

#### Right to withdraw

Your decision to join this study is voluntary. You may quit at any time without notice. We hope you will take part in this study for entire period because we need all the information for conclusions.

#### **Voluntary Consent**

Your decision to join in this study is voluntary. You may quit at any time for any reason without notice. If you have any questions about any part of there study, you have right to ask PhD student or guide to collect information before you sign this consent form. You should not join any other studies where you would assign to receive any medication, special test or any treatment.

Investigator's statement

I have explained the research programme, purpose of the study and possible benefits and risks of participating in the study. The participant was given an opportunity to discuss the procedures and any other queries.

Signature of the investigator with date

#### Participant's Statement

I have clarified that I have read, or had read to me and I understand the description of the study. I voluntarily consent to join in this study.

Signature\_\_\_\_\_

Date\_\_\_\_\_

Name\_\_\_\_\_

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