Metabolic Syndrome Evaluation Form (MSE)

The Metabolic Syndrome Evaluation Form evaluates the presence and severity of the five components that in combination present metabolic syndrome. The five components include hyperglycemia, hypertension, expanded waist circumference, elevated triglycerides and low high density lipid levels. Participants that meet three of the five criteria are considered having metabolic syndrome.

The Metabolic Syndrome Evaluation Form (MSE) should be completed for all PNRR research participants. For evaluation of hyperglycemia and dyslipidemia, the medical history of a participant should be considered, not just the most recent laboratory testing results.

GENERAL INFORMATION

- **Subject ID:** five-digit PNRR subject ID assigned to research participant
- **Sex:** genetic sex of the PNRR participant
- **Year of visit:** year of the visit this PNW form is associated with
- **Year of birth:** year the PNRR participant was born

HYPERGLYCEMIA

Note: *most recent HbA1c value entered in the PNW CRF is displayed*

1. **Diagnosis of hyperglycemia:**
   - **Yes:** participant fulfills one of these criteria:
     i. Recorded clinical diagnosis of Diabetes Mellitus type 1 or type 2,
     ii. Recorded clinical diagnosis of impaired glucose tolerance (IGT),
     iii. past impaired fasting glucose (IFG) of ≥100 mg/dL (with confirmed fasting),
     iv. past HbA1C ≥5.7%,
     v. past elevated 2-hour blood glucose levels ≥140 mg/dL during 2-hour Oral Glucose Tolerance Test (2OGTT)
   - **No:** participant does not have diagnosis of hyperglycemia

2. **Type/severity of hyperglycemia:**
   - **Pre-diabetes criteria:**
     i. diagnosis of IGT (2-hr OGTT ≥140, but <200 mg/dL);
     ii. past IFG (fasting glucose ≥100 but ≤125 mg/dL), confirmed fasting;
     iii. elevated current or past HbA1c (≥5.7, but never >6.4);
     iv. does not take any other glycemic control medications besides metformin, dulaglutide or piglitazone (*Note: if participant takes dulaglutide or piglitazone, diagnosis should be discussed with enrolling physician to make correct distinction if participant has prediabetes or should be considered having DM type 2*);
     v. enrolling physician indicates that participant has prediabetes in exam note.
   - **DM Type 2:** participant fulfills one of these criteria:

i. past HbA1C of ≥6.5%;
ii. past IFG >125 mg/dL while confirmed fasting;
iii. taking ≥1000 mg Metformin QD; or
iv. taking medications with indication of DM Type 2 in table below

- **DM Type 1:** participant carrying diagnosis of DM type 1

Note: *Depending on which type of hyperglycemia was selected, questions 3 and 4 will be tailored towards the type of hyperglycemia. If DM Type 1 is selected, question 3 does not appear because all DM Type 1 participants have to use insulin.*

3.a Medications taken by participant for Prediabetes:

- **No medications:** participant does not take any medications to control blood sugar levels.
- **Low dose Metformin:** participant takes Metformin 500 mg QD or BID, but no other medications to control blood sugar levels.
- **Metformin plus dulaglutide or piglitazone** *(must be confirmed with enrolling physician that participant is still considered prediabetic and not DM Type 2)*
- **Unknown:** daily medication intake is unknown

Note: *If participant takes any other glycemic medications besides metformin, dulaglutide, or piglitazone, the "type/severity of hyperglycemia" must be changed to DM type 2 (or type 1)*

3.b Medications taken by participants for DM type 2:

- **No medications:** participant does not take medication for hyperglycemia
- **Metformin only:** hyperglycemia is controlled with only taking metformin; no other medications regularly prescribed to lower blood sugar levels
- **Metformin and other medications (not insulin):** participant has prescription of at least one hyperglycemic medication other than insulin or metformin. A list of commonly prescribed hyperglycemic medications is provided below.
- **Insulin (and other hyperglycemic medications):** participant has prescription of at least one insulin-containing medication.

Table 1: Common Diabetes / Prediabetes Medications

Generic Name	Brand Name	Indication
Alogliptin	Alogliptin	DM type 2
Canagliflozin	Invokana	DM type 2
Dapagliflozin	Farxiga	DM type 2
Dulaglutide	Trulicity	Prediabetes or DM type 2
Empagliflozin	Jardiance	DM type 2
Exenatide	Bydureon, Byetta	DM type 2
Glimepiride	Amaryl	DM type 2
Glipizide	Glucotrol	DM type 2

Glyburide	Diabeta	DM type 2
Insulin aspart	Novolog	DM type 1 or DM type 2
Insulin degludec	Tresiba	DM type 1 or DM type 2
Insulin detemir	Levemir	DM type 2
Insulin glargine	Lantus, Basaglar, Toujeo	DM type 2
Insulin glargine-yfgn	Semglee	DM type 2
Insulin lispro	Humalog	DM type 2
Insulin N	Novolin N, Humulin N	DM type 2
Insulin R	Novolin R, Humulin R	DM type 2
Linagliptin	Tradjenta	DM type 2
Liraglutide	Victoza, Saxenda	DM type 2
Metformin hydrochloride	Glucophage, Glumetza	DM type 2
Nateglinide	Starlix	DM type 2
Piglitazone	Actos	Prediabetes or DM type 2
Pramlinitide	Symlin Pen	DM type 1
Saxagliptin	Onglyza	DM type 2
Semaglutide	Ozempic	DM type 2
Sitagliptin and metformin	Janumet	DM type 1 or DM type 2
Sitagliptin	Januvia	DM type 2
Repaglinide	Prandin	DM type 2

4. Time elapsed since participant was diagnosed with diabetes or prediabetes:

- Number of years to be entered, with one decimal, e.g 5.5 years

  If information is not available in the medical records, participant should be asked to estimate the time since his/her diagnosis and that information should be entered (e.g. participant answer “at least 6 years”, 6.0 should be entered

The following set of questions only appear when DM type 2 was selected:

5. Was participant diagnosed with Prediabetes prior to DM type 2 diagnosis?

Note: *information is only requested for participants with diagnosis of DM Type 2*

- Years since diagnosis of prediabetes, e.g. 8.0

  Participant should be asked if they had diagnosis of prediabetes prior to their diagnosis of DM type 2. If participant confirms that they had diagnosis of prediabetes, years since initial diagnosis of prediabetes (in regard to enrollment visit) should be entered.

6. Participant’s medical complications from diabetes or pre-diabetic hyperglycemia:

Note: *enrolling physician should be consulted to determine if there are complications from diagnosis of DM or if these conditions have other causes*

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- **None:** participant has none of the diagnosis on records, takes no medication to treat any of the conditions and lab testing results are in normal range
- **Renal insufficiency:** to be checked if participant fulfills one of the following criteria:
  i. entered creatinine level is >1.3 mg/dL;
  ii. glomerular filtration rate (GFR) <60 mL/min/1.73m^2;
  iii. participant has diagnosis of kidney or renal failure;
  iv. participant takes medication to treat renal failure (see table below).
- **Retinal, macular or lens-based eye disease:**
  i. participant has diagnosis of retinopathy, macular edema, or cataracts (or past cataracts surgeries);
  ii. participant takes medication to treat glaucoma (see table below).
- **Coronary artery disease:**
  i. participant has diagnosis of coronary artery disease (CAD), atherosclerosis, angina or arrhythmia;
  ii. participant had past heart attack, stent or bypass surgeries;
  iii. participant takes medications to treat CAD (see table below).
- **Vasculopathy:**
  i. participant carries diagnosis of common vascular disorders such as deep vein thrombosis (DVT), stroke, pulmonary embolus (PE), peripheral arterial disease (PAD), or livedoid vasculopathy;
  ii. participant takes medication to treat vasculopathy (see table below).
- **Unknown:** information not available

Glaucoma

Generic Name	Brand Name
Betaxolol	Betoptic
Bimatroprost	Lumigan
Latanoprost	Xalatan
Latanoprostene	Vyzulta
Tafluprost	Zioptan
Timolol	Betimol, Istalol, Timoptic
Travoprost	Travatan

Coronary Artery Disease

Generic Name	Brand Name
Aspirin (>81 mg)	n/a
Clopidogrel	Plavix
Eptifibatide	Integrilin
Nitroglycerin	n/a
Ranolazine	n/a
Ticlopidine	Ticlid

Renal Insufficiency

Generic Name	Brand Name
Ethacrynic acid	Edecrin Sodium Edcrin
Furosemide	Lasix
Torsemide	Demadex

Vasculopathy

Generic Name	Brand Name
Apixaban	Eliquis
Atrixtra	Fondaparinux
Betrixaban	BEVYXXA
Dabigatran	Pradaxa
Edoxaban	Savaysa
Heparin	n/a
Pentoxifylline	Trentol
Rivaroxaban	Xarelto
Warfarin	Coumadin

6. **Physician assessment of glycemic control:**

   This assessment should be done by the enrolling physician and it should be done considering the entire medical history of hyperglycemia.
   - Well controlled: HbA1c consistently <7.0%
   - Moderately controlled: HbA1c 7.0 - 9.0%
   - Poorly controlled: past HbA1c >9.0%

7. **Past HbA1C testing:**

   Note: *most recent HbA1c value entered in PNW-CRF should not be re-entered here.*

   Past HbA1c values, the represent the medical history of hyperglycemia should be provided. For example, when participant has DM type 2 for the past 10 years, then ideally, HbA1c from 4, 7 and 10 years ago would be provided.

HYPERTENSION

1. **Medication(s) taken by participant for hypertension:**

   - **None:** participant does not take any antihypertensive drugs
   - **One HTN medication:** participant takes one antihypertensive drug
   - **Two HTN medications:** participant takes two antihypertensive drugs
   - **Three or more HTN medications:** participant takes minimum of three antihypertensive drugs

Commonly prescribed hypertensive medications:

Generic Name	Brand Name		Generic Name	Brand Name
Acebutolol	Sectral		Lisinopril	Prinivil, Zestril
Aldactone + HCTZ	Aldactazide		Losartan	Cozaar
Aliskiren	Tekturna		Metoprolol Succinate	Toprol XL
Atenolol	Tenormin		Metoprolol Tartrate	Lopressor
Azilsartan	Edarbi		Nadolol	Corgard
Benazepril	Lotensin		Nebivolol	Bystolic
Bumetanide	Bumex		Nifedipine	Procardia, Adalat
Candesartan	Atacand		Propranolol	Inderal
Carvedilol	Coreg		Quinapril	Accupril
Chlorthalidone	Hygroton		Ramipril	Altace
Clonidine	Catapres		Spironolactone	Aldactone
Diltiazem	Cardiazem, Tiazac, Dilacor		Telmisartan	Micardis
Doxazosin	Cardura		Triamterene	Dyrenium
Enalapril	Vasotec		Triamterene + HCTZ	Dyazide, Maxide
Fosinopril	Monopril		Valsartan	Diovan
Furosemide	Lasix		Telmisartan	Micardis
Hydralazine	Apresoline		Verapamil	Verelan, Calan
Irbesartan	Avapro			

2. **Systolic BP on day of PNRR visit:** Systolic blood pressure reading in mmHg

3. **Diastolic BP on day of PNRR visit:** Diastolic blood pressure reading in mmHg

Note: *only blood pressure measurements taken after a minimum of 5 minutes sitting should be recorded in PNRR. If blood pressure reading is not available from day of study visit, it can be obtained within 90 days of PNRR study visit*

OVERWEIGHT / OBESITY

Note: *BMI, calculated from entered weight and height in PEF-CRF is displayed*

Note: *For particpants who are considered obese, both "obese" and "overweight" should be checked and time elapse since diagnosis should be provided for both conditions.*

1. **Is the participant overweight or obese?**

- **No:** participant has a BMI <27
- **Yes, overweight (BMI ≥27)**
- **Yes, obese (BMI ≥30)**

2.a Years since participant is overweight

Number of years participant is overweight should be entered, e.g. "33" for 33 years.

2.b Years since participant is obese

Number of years participant is obese to be entered, e.g. "22" for 22 years.

The best practice to obtain information since when participant is obese and/or overweight is by asking the participant when they weight more than the weight that corresponds to BMI 27 and 30 based on their height.

Note: *as most Americans are not familiar with metric units, the weight reference question should be asked in reference to pounds (lbs). To convert kg to lbs, the weight in kilograms must be multiplied by a factor of 2.20462 (or 2.2 for short).*

DYSLIPIDEMIA

Note: *Triglycerides and high-density cholesterol (HDL) testing results from PNW-CRF are displayed.*

1. **Diagnosis of Dyslipidemia:**

- **Yes:** participant fulfills at least one of the following criteria:
  i. participant has hypertriglyceridemia (triglycerides >150mg/dL),
  ii. participant has abnormal low high-density lipid (HDL) levels: <40mg/dL for men and, <50mg/dL for women;
  iii. participant takes triglyceride-lowering medication;

iv. participant takes high dosage of lipid-lowering drugs (statins), see table below.

- **No:** participant does have normal lipid profile and take lower dosages of lipid-lowering drugs as usually prescribed for hypercholesteremia
- **Unknown:** not feasible to determine if participant has dyslipidemia based on the available information

2. Type of dyslipidemia diagnosed in participant:

- **Elevated triglycerides (>150):** participant had elevated triglycerides of >150 mg/dL in at least one lipid profile during the past 36 months
- **Low HDL levels (<40 for men, <50 for women):** participant had low HDL level in at least one lipid profile during the past 36 months
- **Takes triglyceride-lowering medication:** participant takes triglyceride lowering agent (list of triglyceride lowering medications provided below)
- **Takes low intensity statin dose:** participant low dose statin (see table below)
- **Takes high intensity statin dose:** participant takes high dose statin (see table below) or has prescription (taking) multiple statins
- **Unknown:** neither lipid profile nor medication list is available for this participant

Commonly prescribed statins and their low and high dosages

Generic Name	Brand Name	Low dosage	High Dosage
Atorvastatin	Lipitor	10-20 mg	40-80 mg
Fluvastatin	Lescol	20-40 mg	80 mg
Lovastatin	Mevacor Altoprev	10-40 mg	60-80 mg
Pravastatin	Pravachol	10-40 mg	80 mg
Rosuvastatin	Crestor	5-10 mg	20-40 mg
Simvastatin	Zocor	5-40 mg	80 mg

Triglyceride lowering agents

Generic Name	Brand Name	
Bezafibrate	Bezalip	
Ezetimibe	Zetia	
Fenofibrate	Antara Fenoglide Lipofen Tricor Triglide	
Fenofibric acid	Fibricor Trilipix	
Gemfibrozil	Lopid	
Icosapent ethyl	Vascepa	
Niacin*	Vitamin B3	
Omega-3 fatty acids*		

***Note:** for participants taking Niacin or Omega-3 fatty acids, it should be confirmed that they are taking it to lower their triglyceride levels and not for other reasons such as heart health.

***Note:** If question about diagnosis of dyslipidemia is answered negatively or as unknown, a pop-up question appears asking if participant takes statin.*

3. **Does participant take statin?**
   - **No:** participant does not take statin
   - **Yes, low intensity statin dose:** prescription is listed as low dosage (see table)
   - **Yes, high intensity statin dose:** prescription is listed as high dosage (see table)

EXERCISE

Note: *time the participant exercises should be recorded. Work related activities, or housekeeping does not count as exercise. In regard to playing golf, only time swinging and walking should be counted.*

1. **Does the participant exercise?**
   - **Yes:** participant dedicates time to exercise.
   - **No:** participant does not exercise.
   - **Unknown:** no information available about exercise habits of this participant.

2. **Total number of minutes exercising per week:**
   Minutes of exercises per week reported by participant – total of all exercises (including aerobic exercise). If participant reports different weekly exercising routines, the average per week should be reported.

3. **Total number of minutes of aerobic exercise per week:**
   Time the participant is performing aerobic exercises, such as jogging, power walking, treadmill, stationary bike, elliptical, swimming, water gymnastics or aerobics. Activities during which the participant "breaks a light sweat" or is a little short of breath are considered aerobic exercise. The weekly average the participant spends on performing aerobic exercises should be reported.

METABOLIC SYNDROME STATUS

Does participant have metabolic syndrome?

- **Yes:** participant meets three (or more) out of the five criteria's that define metabolic syndrome (hyperglycemia, hypertension, overweight/obese, elevated triglycerides, low HDL)
- **No:** participant meets two or less criteria for metabolic syndrome.