

## Objectives

- Define the difference between pre-screening and screening
- Describe the ways pre-screening can be conducted
- Describe the ways screening can be conducted



## Pre-Screening vs Screening

Ē



# Pre-Screening



### How is pre-screening conducted?

- EMR/medical chart review (common)
- Participant Discussion (uncommon)

### What information can be collected?

- Data related to inclusion/exclusion criteria
- Non-medical feasibility information (e.g., ability to attend all study visits)

### What should be submitted to the IRB?

- PHI Prepatory to Research Request
- HIPAA Waiver Request



## Screening

SCREENING **Informed Consent** Fnrollment

### How is screening conducted?

- EMR/medical chart review
- Participant Discussion
- Medical procedures (e.g., lab work)

### What should be submitted to the IRB?

- Protocol describing instruments or procedures used to assess inclusion/exclusion criteria
- Copies of any instruments to be used for screening purposes



# Screening Exercise

**Study Title:** Occurrence of Type 2 Diabetes in Adult Women Who Were Diagnosed with Gestational Diabetes in Multiple Pregnancies

### **Inclusion Criteria**

- > 18 years of age
- Female at birth
- Multiple pregnancies
- Multiple diagnoses of Gestational Diabetes
- Type 2 Diabetes diagnosis post-partum
- No pre-partum diagnosis of Type 1 or Type 2 Diabetes
- No current pregnancy diagnosis

### **Exclusion Criteria**

- < 18 years of age
- Male at birth
- No or single pregnancy diagnosis
- No history of gestational diabetes
- No history of Type 2 diabetes post-partum
- Pre-partum diagnosis of Type 1 or Type 2 Diabetes
- Currently Pregnant
- Prisoners





# Screening Exercise

Subject ID	Date of Birth	Sex	Diagnoses	Notes
001	10/22/1964	F	Multiple Gestation (1994) Gestational Diabetes (1994) Type 2 Diabetes (2005)	
002	08/24/1960	F	Single Gestation (1994) Single Gestation (2000) Gestational Diabetes (1994, 2000) Type 2 Diabetes (2001)	Prisoner
003	05/07/1994	F	Single Gestation (2020) Singles Gestation (2022) Gestational Diabetes (2020, 2022) Type 2 Diabetes (2024)	
004	07/12/2009	F	Type 1 Diabetes (2013) Single Gestation (2023) Single Gestation (2023) Gestational Diabetes (2023)	
006	04/02/2001	F	Single Gestation (2017) Multiple Gestation (2021) Gestational Diabetes (2017, 2021) Type 2 Diabetes (2023)	
007	12/18/2007	F	Single Gestation (2023) Gestational Diabetes (2023) Type 2 Diabetes (2023)	15

### 

# Screening Exercise

Subject ID	Date of Birth	Sex	Diagnoses	Notes	
001	10/22/1964	F	Multiple Gestation (1994) Gestational Diabetes (1994) Type 2 Diabetes (2005)		
002	08/24/1960	F	Single Gestation (1994) Single Gestation (2000) Gestational Diabetes (1994, 2000) Type 2 Diabetes (2001)	Prisoner	
003	05/07/1994	F	Single Gestation (2020) Singles Gestation (2022) Gestational Diabetes (2020, 2022) Type 2 Diabetes (2024)		
004	07/12/2009	F	Type 1 Diabetes (2013) Single Gestation (2023) Single Gestation (2023) Gestational Diabetes (2023)		
006	04/02/2001	F	Single Gestation (2017) Multiple Gestation (2021) Gestational Diabetes (2017, 2021) Type 2 Diabetes (2023)		
007	12/18/2007	F	Single Gestation (2023) Gestational Diabetes (2023) Type 2 Diabetes (2023)		IS

## LSU Health Coordinator Competencies

- Onboarding
- Ethical Standards
- Protocol Compliance
- Informed Consent
- Patient Screening & Recruitment
- Management of Patients
- Documentation & Document Management
- Data Management & Information Technology
- Financial Stewardship
- Leadership & Professional Development

