

Study Subject ID#: _____	
Date of Birth: _____	Gender: Male [] Female []
Informed Consent Date (DD-MMM_YYYY) and Time (24hr Clock): _____	
Date Sample Collected(DD-MMM_YYYY) and Time(24hr Clock): _____	

Demographics

Ethnicity:	<input type="checkbox"/> Hispanic	<input type="checkbox"/> Non-Hispanic
Race:	<input type="checkbox"/> White	<input type="checkbox"/> Black/African American
	<input type="checkbox"/> Asian/Pacific Islander	<input type="checkbox"/> American Indian/Alaska Native
	<input type="checkbox"/> Unknown	<input type="checkbox"/> Other(specify): _____

History of Opiod Prescription

Subject has been prescribed Opiod(s) for a minimum of 5 consecutive days: YES NO

DSM 5 classification

<input type="checkbox"/> Mild
<input type="checkbox"/> Moderate
<input type="checkbox"/> Severe

All the information contained on this page is accurate.

Signature : _____ Date (DD-MMM-YYYY): _____

Collection Site: _____	
Study Subject ID#: _____	
Date of Birth: _____	Gender: Male [] Female [] Other []
Informed Consent Date (DD-MMM_YYYY) and Time (24hr Clock): _____	
Date Sample Collected(DD-MMM_YYYY) and Time(24hr Clock): _____	

Demographics

State Of Residence _____

Marital Status: Single (Never Married) Married or in sustained committed relationship Divorced Widowed

Ethnicity: Hispanic Non-Hispanic
Race: White Black/African American
 Asian/Pacific Islander American Indian/Alaska Native
 Unknown Other(specify): _____

Subject has been prescribed Opiod(s) for a minimum of 4 consecutive days: YES NO

Tobacco use (including cigarettes and smokeless tobacco [i.e. chewing tobacco, vaping]): Never Used Former occasional user
 Current Ocasional user Current Daily user
 Former Daily user

DSM 5 classification Mild
 Moderate
 Severe

All the information contained on this page is accurate.

Signature : _____ Date (DD-MMM-YYYY): _____

Collection Site: _____

Study Subject ID#: _____

Date of Birth: _____

Gender: Male [] Female [] Other []

Informed Consent Date (DD-MMM_YYYY) and Time (24hr Clock): _____

Date Sample Collected(DD-MMM_YYYY) and Time(24hr Clock): _____

Demographics

State Of Residence _____

Marital Status: Single (Never Married) Married or in sustained committed relationship Divorced Widowed

Ethnicity: Hispanic Non-Hispanic

Race: White Black/African American
 Asian/Pacific Islander American Indian/Alaska Native
 Unknown Other(specify): _____

Subject has been prescribed Opioid(s) for a minimum of 4 consecutive days and a maximum of 30 consecutive days: YES NO

Month and year of first opioid prescription(MMM_YYYY): _____

Tobacco use (including cigarettes and smokeless tobacco [i.e. chewing tobacco, vaping]):
 Never Used Former occasional user
 Current Occasional user Current Daily user
 Former Daily user

DSM 5 classification
 Mild
 Moderate
 Severe

All the information contained on this page is accurate.

Signature: _____ Date(DD-MMM-YYYY): _____

Case Report Form

(b) (4)

Collection site: _____

Study Subject ID: _____

Inclusion Criteria	Yes	No
1. Subject is at least 18 years old		
2. Subject is able to provide informed consent to participate in the study (Note: a legal representative may NOT provide consent on behalf of the subject.)		
3. Subject has consented to participate in the study		
4. Subject has consented to DNA testing either by signing the informed consent for this study or by past consent		
5. Subject has consented to buccal sample collection in accordance with this study protocol or subject has a DNA sample that meets the DNA requirements of the study as documented by signing the study-specific informed consent		
6. Subject has taken prescription oral opioids for at least 4 consecutive days and not more than 30 consecutive days		

If any answer is in a gray box (**No** for any of #1-#6), then the subject is **NOT** eligible for this study. Otherwise, complete items #7a and #7b below.

Date of qualifying exposure	Month (if known) MMM	Year YYYY
7a. Date subject first took prescription oral opioids for at least 4 consecutive days and not more than 30 consecutive days		

Time since qualifying exposure	Yes	No
7b. Date when the subject first took prescription oral opioids for at least 4 consecutive days and not more than 30 consecutive days (item #7) occurred at least one year ago		

If the answer to item #7b is **No**, then the subject is **NOT** eligible for this study. Otherwise, complete the exclusion criterion immediately below.

Exclusion Criterion	Yes	No
1. Subject has EVER received medical care that included taking prescription oral opioids for more than 30 consecutive days		

If the answer to item Exclusion Criterion #1 is **YES**, then the subject is **NOT** eligible for this study. Otherwise, the subject **IS** eligible for this study.

Informed consent date and time (DD-MMM-YYYY, 24-hour clock): _____
(example 01-NOV-2019 08:35)

Subject collection date and time (DD-MMM-YYYY, 24-hour clock): _____

(b) (4)

Study Subject ID: _____

Subject demographics

Age: _____

State of residence: _____

Gender at birth

Male

Female

Marital status

Single (never married)

Married or in a sustained committed relationship

Divorced

Widowed

Ethnicity

Hispanic

Non-Hispanic

Race

White

Black/African American

Asian/Pacific Islander

American Indian/Alaska native

Unknown

Other (specify): _____

Tobacco use including cigarettes and smokeless tobacco (e.g., chewing tobacco, vaping)

Never used

Former occasional user

Current occasional user

Former daily user

Current daily user

Subject has a DSM-5 diagnosis of Opioid Use Disorder in the medical record?

Yes

No

DSM-5 classification of Opioid Use Disorder

Mild

Moderate

Severe

Not applicable, subject has not been diagnosed with OUD

All the information contained on this Case Report Form is accurate.

Signature : _____ Date (DD-MMM-YYYY): _____