Attachment 1 Study Form 4: Patient Case Report Form (CRF)



Study Subject ID#:		
Date of Birth:	Gender: Male []	Female []
Informed Consent Date (DD-MMM_YYYY) and Time	e (24hr Clock):	
Date Sample Collected(DD-MMM_YYYY) and Time(24hr Clock):	<u></u> s
Demographics		
Ethinicity: Hispanic	Non-Hispanic	
Race: White	Black/African American	
Asian/Pacific Islander	American Indian/Alaska Native	
Unknown	Other(specify):	
<u>History of Opiod Prescription</u> Subject has been prescibed Opiod(s) for a minimum of	f 5 consecutive days: YES	□ NO
DSM 5 classification Mild Moderate Severe		
All the information contained on this page is accurate.		
Signature :	Date (DD-MMM-YYYY):	_

Attachment 1

Study Form 4: Patient Case Report Form (CRF)

Collection Site:	
Study Subject ID#:	
Date of Birth:	Gender: Male [] Female [] Other []
Informed Consent Date (DD-MMM_YYYY) and Time (24	hr Clock):
Date Sample Collected(DD-MMM_YYYYY) and Time(24hi	· Clock):
Demographics	
State Of Residence	
Marital Status: Single (Never Married)	Married or in sustained committed relationship Divorced Widowed
Ethinicity: Hispanic Race: White Asian/Pacific Islander Unknown	Non-Hispanic Black/African American American Indian/Alaska Native Other(specify):
Subject has been prescibed Opiod(s) for a minimum of 4 c	onsecutive days: YES NO
Tobacco use (including cigarettes and smokeless tobacco [i.e. chewing tobacco, vaping]): Never Used Current Ocasional user Former 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):

Attachment 1

Study Form 4: Patient Case Report Form (CRF)

Collection Site:	
Study Subject ID#:	<u>-</u>
Date of Birth:	Gender: Male [] Female [] Other []
Informed Consent Date (DD-MMM_YYYY) and Time (2	24hr Clock):
Date Sample Collected(DD-MMM_YYYY) and Time(24)	hr 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_YYY	(Y):
Гоbассо 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):
thnicity:	Married or in sustained committed relationship

Page 1

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 f 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) Year YYYY Ta. Date subject first took prescription oral opioids for at least 4 consecutive days and not more than 30 consecutive days Time since qualifying exposure 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 f the answer to item #7b is No, then the subject is NOT eligible for this study.	case Report Form			
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Attachment 1

CRF Version 4

Page 2

Female
Married or in a sustained committed relationship
Widowed
Non-Hispanic
Black/African American
American Indian/Alaska native
Other (specify):
nd smokeless tobacco (e.g., chewing tobacco, vaping)
Former occasional user
Former daily user
ioid Use Disorder in the medical record?
☐ No
isorder
Moderate
Not applicable, subject has not been diagnosed with OUD
Case Report Form is accurate.
Date (DD-MMM-YYYY):

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