Form 1: Protocol Inclusion and Exclusion Case Report Form	
Protocol Title:	(b) (4)
Protocol Number:	(b) (4)
Study Site:	To be pre-printed
Subject ID:	To be pre-printed

Notes for Completion

- Complete this case report form for the subject identified on this form (Subject ID).
- The site number and subject ID number are on the top of each page of the form.
- Identify the subject by the study-specific ID number only.
- Use only a blue or black ink pen to complete the form.
- The response to each question must be checked within the box as either "Yes" or "No."
- To complete this form, review all medical history and medical records for the subject available at the site.
- For Question 5a and Question 5b must both be answered.
- For Question 5a, it must be the subject's first exposure and the prescription oral opioid was prescribed to the subject who took the oral opioid for 4-30 days.
- For Question 5b, if the subject was prescribed oral opioids for longer than 30 days, it was for treatment of OUD which was diagnosed according to the DSM-5 criteria.

Inclusion Criteria	YES	NO
1. Subject is at least 18 years old.		
2. Subject or legal representative has consented to participate in the study.		
3. Subject has provided consent for DNA testing (either by signing the informed consent for this study or by past consent). In the latter case, the DNA sample collected in a prior study must meet all requirements for this study.		
4. 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.		
5. Subject was:		
5a. Exposed to prescription oral opioids for a duration of 4-30 consecutive days		
5b. A psychiatrist diagnosed the subject as having OUD according to DSM-5 criteria		
6. The index exposure to prescription oral opioids began at least 1 year prior to enrollment in this study. 6a. Insert date of index exposure: MMM/YYYY ☐☐☐ / ☐☐☐☐		

Form 1: Protocol Inclusion and Exclusion Case Report Form	
Protocol Title:	(b) (4) [redacted]
Protocol Number:	(b) (4) [redacted]
Study Site:	To be pre-printed
Subject ID:	To be pre-printed

Notes for Completion
• For Questions 5a and 6a, the original study documentation should be used to complete these fields. If the month of index exposure is unknown, enter 999 for the month. If the year is unknown, enter 9999 for the year. • For Exclusion Criterion 1, the intent for the "unless a psychiatrist had diagnosed the subject as having OUD according to DSM-5 criteria" was to allow subjects who are being actively treated for OUD (e.g., buprenorphine or methadone) to qualify for the study.

Exclusion Criteria	YES	NO
1. Subject has ever[1] received medical care that included taking oral opioid for more than 30 consecutive days unless a psychiatrist had diagnosed the subject as having OUD according to DSM-5 criteria.		
2. Subject or legal representative is not able to provide consent to participate in the study.		

To be eligible for the study, the subject must have the following responses:

Under Inclusion Criteria:

- *A "yes" response must be checked for Questions 1-4, 5a and Question 6*
- *A "yes" or "no" response may be checked for Question 5b*

Under Exclusion Criteria:

- *A "no" response must be checked for Questions 1 and 2*

[1] The protocol contained a syntax error in that this criterion stated "Subject has never received..." rather than "Subject has ever received...." This syntax error was corrected on this form.

Form 2: Exposure Data to Prescription Oral Opioids Case Report Form	
Protocol Title:	(b) (4)
Protocol Number:	(b) (4)
Study Site:	To be pre-printed
Subject ID:	To be pre-printed
Time Period to Review:	To be pre-printed for each subject (1 calendar year before and after self-reported index exposure)

Notes for Completion

- Complete this case report form for the subject identified on this form (Subject ID).
- The site number and subject ID number are on top of each page of this form.
- Identify the subject by the study-specific ID number only.
- Use only a blue or black ink pen to complete the form.
- Each response must be provided within the boxes.
- To complete this form, review all medical history and medical records available at the site for the subject for the following time period: To be pre-printed.
- Examine the records and medical history for events or procedures consistent where oral opioids may be prescribed for acute pain as part of medical care, such as:
  - Surgical procedures including include knee surgery or any orthopedic surgery, caesarean-section, laparoscopic surgery, appendicitis, cosmetic surgery
  - Dental procedures include wisdom tooth extraction, dental implants, root canal, periodontal disease
  - Accidents or injuries, such as motor vehicle accidents, fractures, burns
- For the medical records, be sure to review all available sections for each encounter, include without limitation: reason for visit (chief complaint), past surgical history, past medical history, prescription history, review of systems, procedure and operative notes, consults, current medications, and summary of findings.
- For question 3, if a medical history or medical record is available that may correlate to the self-reported exposure, but no clear date is available in the medical record or history, please mark possibly.

1. Are medical records and medical history available for this subject for you to review?

☐ Yes ☐ No

If no, stop. If yes, continue to Question 2.

2. What is the format of the medical records and medical history?

☐ Paper

☐ Electronic

☐ Combination of paper and electronic

3. Is there a medical procedure, dental procedure, injury or accident in the medical records or medical history related to the self-exposure date from Form 1?

☐ Yes ☐ Possibly ☐ No

If yes or possibly , continue to Question 4. If no, skip to Question 5.

Form 2: Exposure Data to Prescription Oral Opioids Case Report Form	
Protocol Title:	(b) (4)
Protocol Number:	(b) (4)
Study Site:	To be pre-printed
Subject ID:	To be pre-printed
Time Period to Review:	To be pre-printed for each subject (1 calendar year before and after self-reported index exposure)

4. For the procedure or event identified in Question 4, complete the following questions.

4a. Check the type of event or procedure.

- ☐ Surgical procedure
- ☐ Dental procedure
- ☐ Accident or injury
- ☐ Other

If other, describe:_____

_____

4b. Date of event/procedure:
If month unknown, enter 999.
If year unknown, enter 9999.

☐☐☐/☐☐☐☐
MMM/YYYY

4c. Check the type(s) of medical record where event or procedure was documented.

- ☐ Medical records or history generated at the site
- ☐ Medical records or history available at the site from another healthcare facility

4d. Did the medical records or history indicate that oral opioids were prescribed for that event or procedure?

☐ Yes ☐ No

4e. Is the oral opioid prescription present in the medical records or history (e.g., physical copy, electronic copy, scan, or photograph)?

☐ Yes ☐ No

If yes, enter date of prescription
If month unknown, enter 999
If year unknown, enter 9999

☐☐☐/☐☐☐☐
MMM/YYYY

5. If no event or procedure was identified in the medical history or medical records, check the reason why.

- ☐ Medical care at practice for a limited time or intermittent
- ☐ Data regarding procedures and events not included in the medical records or medical history
- ☐ Other

If other, describe:_____

_____

Form 3: Comorbidities Case Report Form	
Protocol Title:	(b) (4)
Protocol Number:	(b) (4)
Study Site:	To be pre-printed
Subject ID:	To be pre-printed

Notes for Completion

- Complete this case report form for the subject identified on this form (Subject ID).
- The site number and subject ID number are provided on the top of each page of this form.
- Identify the subject by the study-specific ID number only.
- Use only a blue or black ink pen to complete the form.
- The response to each item must be checked within the boxes.
- To complete this form, review all medical history and medical records for the subject, available at the site.
- For the medical records, review all available sections for each encounter, including without limitation: reason for visit (chief complaint), past surgical history, past medical history, prescription history, review of systems, procedure and operative notes, radiology reports, consults, current medications, and summary of findings.
- For any "yes" response on medical history, complete the date field, using the first date the comorbidity was identified or diagnosed.
- For dates, provide the month/year (MMM/YYYY). If the month is unknown, enter "999." If the year is unknown, enter "9999."

6. Are medical records and medical history available for this subject for you to review?

☐ Yes ☐ No

If no, stop. If yes, continue to Question 2.

7. What is the format of the medical records and medical history?

☐ Paper

☐ Electronic

☐ Combination of paper and electronic

8. Does the subject have a medical history of:

	Yes	No
Alcohol Use Disorder	☐	☐

If yes, date: MMM/YYYY

☐☐☐/☐☐☐☐

Form 3: Comorbidities Case Report Form	
Protocol Title:	(b) (4)
Protocol Number:	(b) (4)
Study Site:	To be pre-printed
Subject ID:	To be pre-printed

	Yes	No
Anxiety If yes, date: MMM/YYYY ☐☐☐/☐☐☐☐	☐	☐
Bipolar Disorder If yes, date: MMM/YYYY ☐☐☐/☐☐☐☐	☐	☐
Cannabis Use Disorder If yes, date: MMM/YYYY ☐☐☐/☐☐☐☐	☐	☐
Depression If yes, date: MMM/YYYY ☐☐☐/☐☐☐☐	☐	☐

	Yes	No
Schizophrenia If yes, date: MMM/YYYY ☐☐☐/☐☐☐☐	☐	☐
Substance Use Disorder Other than Opioid, Alcohol or Cannabis If yes, date: MMM/YYYY ☐☐☐/☐☐☐☐ **Identify Other Substance:**_____ _____	☐	☐

Signature Page	
Protocol Title:	(b) (4)
Protocol Number:	(b) (4)
Study Site:	To be pre-printed
Subject ID:	To be pre-printed

Confirmation of Completion and Review:

By signing this form, you declare that the data provided on Form 1, Form 2, and Form 3 are to the best of your knowledge accurate and completed in accordance with the Sponsor's instructions.

Name:_____

Signature: _____

Date: _____(DD/MMM/YYYY)