CTN-0069 Annotated CRFs - Segment C **NIDA Clinical Trials Network** Adverse Event (AD1) Web Version: 1.0; 4.01; 05-28-19 Adverse event onset date (AEDATE): Event number (AESEQNO): This adverse event has been closed by the Medical Reviewer and may no longer be updated. 1. Adverse event name:(A1DESCPT) 2. Date site became aware of the event:(A1AWARDT) (mm/dd/yyyy) 3. Severity of event: (A1SEVRTY) 1-Grade 1 - Mild 2-Grade 2 - Moderate 3-Grade 3 - Severe 4. Outcome of event:(A1OUTCM) 1-Ongoing 2-Resolved without sequelae 3-Resolved with sequelae 4-Resolved by convention 5-Death Except for "None of the following", all selections in the question below will designate this as a Serious Adverse Event (SAE). The Serious Adverse Event Summary (AD2) form should be completed for all Serious Adverse Events reported.

5. Was this event associated with:(A1ASSOC) 0-None of the following 1-Death 2-Life-threatening event 2-Inpatient admission to hospital or prolongation of existing hospitalization
4-Persistent or significant incapacity
\*Additional Options Listed Below a. If "Death," was it related to an overdose event?(A1DTHODE) ☐ 0-No ☐ 1-Yes ☐ 97-Unknown b. If "Death", date of death:(A1DTHDT) (mm/dd/yyyy) Comments:(AD1COMM)

## Additional Selection Options for AD1

Event number (AESEQNO) (key field):
01-1st Adverse Event of the day
02-2nd Adverse Event of the day
03-3rd Adverse Event of the day
04-4th Adverse Event of the day
05-5th Adverse Event of the day
06-6th Adverse Event of the day
07-7th Adverse Event of the day
08-8th Adverse Event of the day
09-9th Adverse Event of the day

Was this event associated with:
5-Congenital anomaly or birth defect
6-Important medical event that required intervention to prevent any of the above

CTN-0069 Annotated CRFs - Seg	gment C					
	NIDA	Clinica	ıl Trials Network			
	Serious Adv	verse E	Event Summary (AD2)			Walt Version 4 0: 2 00: 40 02
Adverse event onset date (AEDATE):						Web Version: 1.0; 2.00; 10-03-
Event number (AESEQNO):						
This adverse event has been closed by the Medical Reviewer a	and may no longer be updated.					
Initial narrative description of serious adverse event:(A2SUMM)						
2. Relevant past medical history:(A2SAEMHX)		□ 0-No	☐ 1-Yes ☐ 97-Unknown			
Allergies, pregnancy, smoking and alcohol use, hypertension, diabe (A2MEDHX)	etes, epilepsy, depression, etc.					
3. Medications at the time of the event:(A2SAEMED)		□ 0-No	☐ 1-Yes ☐ 97-Unknown			
Medication (Generic Name)	Indication					
(A2_01DNM)	(A2_01DIN)					
(A2_02DNM)	(A2_02DIN)					
(A2_03DNM)	(A2_03DIN)					
(A2_04DNM)	(A2_04DIN)					
(A2_05DNM)	(A2_05DIN)					
(A2_06DNM)	(A2_06DIN)					
(A2_07DNM)	(A2_07DIN)					
(A2_08DNM)	(A2_08DIN)					
(A2_09DNM)	(A2_09DIN)					
(A2_10DNM)	(A2_10DIN)					
4. Treatments for the event:(A2SAETRT)		O-No	☐ 1-Yes ☐ 97-Unknown			
Treatment	Indication		Date Treated (mm/dd/yyyy)			
(A2_1TNME)	(A2_1TIND)		(A2_1LTDT)			
(A2_2TNME)	(A2_2TIND)		(A2_2LTDT)			
(A2_3TNME)	(A2_3TIND)		(A2_3LTDT)			
(A2_4TNME)	(A2_4TIND)		(A2_4LTDT)			
(A2_5TNME)	(A2_5TIND)		(A2_5LTDT)			
Labs/tests performed in conjunction with this event: (A2SAELAB)		□ o No	☐ 1-Yes ☐ 97-Unknown	•		
Lab/Test	Fin	ndings	1-les 297-Olikilowii		Date of Test (mm/dd/yyyy)	
(A2_1LBNM)	(A2_1LBIN)				(MZ_1LBDT)	
(A2_2LBNM)	(A2_2LBIN)				(A2_2LBDT)	
(A2_3LBNM)	(A2_3LBIN)				(A2_3LBDT)	
(A2_4LBNM)	(A2_4LBIN)				(A2_4LBDT)	
(A2_5LBNM)	(A2_5LBIN)				(A2_5LBDT)	
	JI					Ш
6. Follow-up:(A2FOLLUP)						
Include labs/test results as they become available, clinical changes	, consultant diagnosis, etc.					
7. Additional information requested by the Medical Monitor:(A2ADDIN	(F)					
Have all Medical Monitor requests been addressed?(A2RQADD	)R)	1-Yes				
		_ 1-100				

# Additional Selection Options for AD2

Event number (AESEQNO) (key field):
01-1st Adverse Event of the day
02-2nd Adverse Event of the day
03-3rd Adverse Event of the day
04-4th Adverse Event of the day
05-5th Adverse Event of the day
05-6th Adverse Event of the day
07-7th Adverse Event of the day
09-8th Adverse Event of the day
09-9th Adverse Event of the day
10-10th Adverse Event of the day

CTN-0069 Annotated CRFs - Segment C		
	NIDA Clinical Trials Network	
5	Serious Adverse Event Medical Reviewer (AD3)	W. V
Adverse event onset date (AEDATE): Event number (AESEQNO):		Web Version: 1.0; 3.01; 05-28-19
Was this determined to be a serious adverse event?(A3SAE)	□ 0-No □ 1-Yes	
2. Was this event expected?(A3EXPECT)	☐ 0-No ☐ 1-Yes	
<ol> <li>Is this a standard expedited/reportable event?         (i.e., is it serious, unexpected and related to therapy)(A3EXPFDA)         If "No", is this an expedited/reportable event for other reasons?(A3EXPOTH)</li> </ol>	□ 0-No □ 1-Yes	
4. Does the protocol need to be modified based on this event?(A3MPROT)	□ 0-No □ 1-Yes	
Does the consent form need to be modified based on this event?(A3MCNST)	□ 0-No □ 1-Yes □ 0-No □ 1-Yes	
6. Is the review complete?(A3REVDNE)	0-No 1-Yes	
If "No", what additional information is required:(A3ADDINF)		
Assessed by:(A3ASRID)	(initials)	
Reviewed by:(A3REVID)	(initials)	

Comments:(A3COMM)

# **Additional Selection Options for AD3**

- Event number (AESEQNO) (key field):
  01-1st Adverse Event of the day
  02-2nd Adverse Event of the day
  03-3rd Adverse Event of the day
  04-4th Adverse Event of the day
  05-5th Adverse Event of the day
  05-6th Adverse Event of the day
  07-7th Adverse Event of the day
  09-8th Adverse Event of the day
  09-9th Adverse Event of the day
  10-10th Adverse Event of the day

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CTN-0069 Annotated CRFs - Segment C	
NID	DA Clinical Trials Network
Critica	al Action Checklist (CAC)
Segment (PROTSEG): C Visit number (VISNO):	<b>Web Version: 1.0</b> ; 2.00; 06-14-1
Complete this checklist based on chart review.  1. Was buprenorphine administered in the ED, prescribed at discharge and/or provided for take home administration? (CAEDBUP)	□ 0-No □ 1-Yes
2. Urine toxicology obtained:(CATOXOBT)	□ 0-No □ 1-Yes
3. Urine toxicology documented as positive for opioids:(CATOXDOC)	□ 0-No □ 1-Yes
4. Liver functions tests (AST, ALT) obtained:(CALFTOBT)	□ 0-No □ 1-Yes

□ 0-No □ 1-Yes

☐ 0-No ☐ 1-Yes □ 0-No □ 1-Yes □ 0-No □ 1-Yes

Comments:(CACCOMM)

5. Documentation that patient met criteria for moderate to severe opioid use disorder:(CAOUDDOC)

 $7.\ \ Documentation\ that\ buprenorphine\ education\ and\ induction\ instructions\ provided: \textit{(CAEDUDOC)}$ 8. Direct referral for ongoing medication assisted treatment documented: (CAMATDOC)

6. Formal assessment of opioid withdrawal severity (e.g., COWS) documented:(CACOWDOC)

CTN-0069 Annotated CRFs - Segment C		
	NIDA Clinical Trials Network	
	Crime and Criminal Justice (CCJ)	
Segment (PROTSEG): C Visit number (VISNO):		Web Version: 1.0; 1.00; 03-27-17
Have you been incarcerated within the past 12 months?(CCINC12)  If "Yes", how many days?(CCINC12D)	0-No 1-Yes (xxx)	
The next questions apply only to the 30 days immediately following your ED enrollment visit.  2. Have you been incarcerated in the past 30 days?(CCINC30)  If "Yes", how many days?(CCINC30D)	□ 0-No □ 1-Yes	
3. How many times in the past 30 days have you committed the following crimes? a. Dealing narcotics:(CCNARCO)	(xxx)	
b. Vandalism:(CCVANDAL) c. Stolen property:(CCPROPTY)	(xxxx)	
d. Forgery/counterfeiting:(CCFORGE) e. Fraud:(CCFRAUD)	(xxx)	
f. Larceny/theft:(CCLARLEF) g. Household burglary:(CCBURGLR)	(xxx)	

(xxx)

(xxx)

(xxx)

(xx)

(xx)

(xx)

4. How many days in the last 30 days have you been in contact (either initiated by you or by the legal system) with the court, criminal justice system, or probation/parole officer?

a. Court:(CCCNTCRT)

(xx)

h. Robbery:(CCROBBRY)

j. Homicide:(CCHOMICD)

Comments:(CCJCOMM)

i. Rape/sexual assault:(CCRAPE)

b. Criminal justice system:(CCCNTCJS)

c. Probation/parole officer:(CCCNTPRO)

CTN-0069 Annotated CRFs - Segment C	
NII	DA Clinical Trials Network

# Demographics (DEM)

Web Version: 1.0; 6.01; 01-07-21

Date of birth:(DEBRTHDT)	(mm/dd/yyyy)
Age:(DEAGE)	(xx)
Age:(DEAGE)	(xx)
Sex:(DESEX)	☐ 1-Male ☐ 2-Female ☐ 97-Don't know ☐ 98-Refused to answer
What gender do you identify with?(DEGENDER)	□ 01-Male □ 02-Female □ 99-Other □ 98-Prefer not to answer
Does the participant consider him or herself to be Hispanic/Latino?(DEHISPNC)	□ 0-No □ 1-Yes □ 97-Don't know □ 98-Refused to answer
If "Yes", indicate the group that represents his or her Hispanic origin or ancestry: (DEHISPSP)	1-Puerto Rican 2-Dominican (Republic) 3-Mexican/Mexican American 5-Chicano 6-Cuban/Cuban American *Additional Options Listed Below
What race does the participant consider him or herself to represent? (Check all that apply)  American Indian or Alaska Native:(DEAMEIND)	□ 1-
Asian: (DEASIAN)	
Asian Indian: (DEASAIND)	□ 1 <b>-</b>
Chinese:(DECHINA)	
Filipino:(DEFILIPN)	□ 1-
Japanese:(DEJAPAN)	□ 1-
Korean: (DEKOREA)	□ 1-
Vietnamese:(DEVIETNM)	
Specify other Asian:(DEASIAOT)	
Black or African American:(DEBLACK)	□ 1-
Native Hawaiian or Pacific Islander:(DEHAWAII)	
Native Hawaiian:(DENATHAW)	
Guamanian or Chamorro:(DEGUAM)	
Samoan:(DESAMOAN)	
Specify other Pacific Islander: (DEPACISO)	
White:(DEWHITE)	<u></u> 1-
Some other race:(DERACEOT)	1- Specify:(DERACESP)
-or-	Spoony,(BE1710EE7)
Don't know:(DERACEDK)	□ 1-
Refused:(DERACERF)	□ 1-
What is the highest grade or level of school the participant has completed or the highest degree they have received? (DEEDUCTN)	00-Never attended / kindergarten only a 01-1st grade 02-2nd grade 03-3rd grade 04-4th grade *Additional Options Listed Below
We would like to know about what the participant does — is he/she working now, looking for work, retired, keeping house, a student, or what?( <i>DEJOB</i> )	01-Working now 02-Only temporarily laid off, sick leave, or maternity leave 03-Looking for work, unemployed 04-Retired 05-Disabled, permanently or temporarily *Additional Options Listed Below
If "Other", specify:(DEJOBSP)	
Is the participant currently married, widowed, divorced, separated, never married, or living with a partner?(DEMARTL)	01-Married 02-Widowed 03-Divorced 04-Separated 05-Never married *Additional Options Listed Below
Comments:(DEMCOMM)	

# **Additional Selection Options for DEM**

If "Yes", indicate the group that represents his or her Hispanic origin or ancestry: 8-Central or South American 9-Other Latin American 99-Other Hispanic or Latino 98-Refused 97-Don't know 97-Don't know

What is the highest grade or level of school the participant has completed or the highest degree they have received?
05-5th grade
05-6th grade
07-7th grade
08-8th grade
09-9th grade
10-10th grade
11-11th grade
11-11th grade
11-11th grade
11-11th grade, no diploma
13-High school graduate
14-4CED or equivalent
15-Some college, no degree
15-Some college, no degree
17-Associate's degree: occupational, technical, or vocational program
17-Associate's degree: cademic program
18-Bachelor's degree (e.g., BA, AB, BS, BBA)
19-Master's degree (e.g., BA, AB, BS, BBA)
19-Master's degree (e.g., BA, AB, SH, BMA)
20-Professional school degree (e.g., MD, DDS, DVM, JD)
21-Doctoral degree (e.g., PhD, EdD)
98-Refused
97-Don't know

We would like to know about what the participant does -- is he/she working now, looking for work, retired, keeping hou

We would like to know about what the participant does -- is he/she working now, looking for work, retired, keeping house, a student, or what? 06-Keeping house 07-Student 99-Other

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CTN-0069 Annotated CRFs - Segment C	
NIDA Clinical Trials Network	

# Additional Demographics (DM1)

Web Version: 1.0; 2.00; 06-18-18

Segment ( <i>PROTSEG</i> ): C Visit number (VISNO):	
1. Are you currently covered by health insurance or health coverage plans? This does not include plans that pay for only one type of service (such as, nursing home care, accidents, family planning, or dental care) and plans that only provide extra cash when hospitalized. (DMHEALTH) If "Yes" indicate the type of plan:	□ 0-No □ 1-Yes
a. Insurance through a current or former employer or union (of yours or another family member's):	☐ 1-Covered ☐ 2-Not covered ☐ 3-Not sure
This would include COBRA coverage.(DMINSEMP)  b. Insurance purchased directly from an insurance company (by you or another family member):	☐ 1-Covered ☐ 2-Not covered ☐ 3-Not sure
This would include coverage purchased through an exchange or marketplace, such as HealthCare.gov.(DMINSCOM)  If "Covered", does the coverage have a state-specific program name?(DMSTCO)	□ 0-No □ 1-Yes □ 2-Not sure
If "Yes", specify the name:(DMSTCOSP)	
c. Medicare, for people 65 and older, or people with certain disabilities:(DMINSCAR)	☐ 1-Covered ☐ 2-Not covered ☐ 3-Not sure
If "Covered", does the coverage have a state-specific program name?(DMSTCR)	□ 0-No □ 1-Yes □ 2-Not sure
If "Yes", specify the name:(DMSTCRSP)	
d. Medicaid, Medical Assistance (MA), the Children's Health Insurance Program (CHIP), or any kind of state or government-	☐ 1-Covered ☐ 2-Not covered ☐ 3-Not sure
sponsored assistance plan based on income or a disability:(DMINSCAI)  If "Covered", does the coverage have a state-specific program name?(DMSTCD)	□ 0-No □ 1-Yes □ 2-Not sure
If "Yes", specify the name:(DMSTCDSP)	
e. TRICARE or other military health care, including VA health care:(DMINSTRI)	☐ 1-Covered ☐ 2-Not covered ☐ 3-Not sure
f. Indian Health Service:(DMINSIHS)	☐ 1-Covered ☐ 2-Not covered ☐ 3-Not sure
g. Any other type of health insurance coverage or health coverage plan:(DMINSOTH)  If "Covered" by another type, specify:(DMOTSP)	☐ 1-Covered ☐ 2-Not covered ☐ 3-Not sure
2. What has been your usual employment pattern in the past 12 months? (DMEMPLOY)  3. What is your combined household income? (DMINCOME)	1-Full time (35+ hrs) 2-Part time (regular hours) 3-Part time (irregular hours) 4-Student 5-Military service *Additional Options Listed Below  1-<\$35,000 2-\$35,001-\$50,000 3-\$50,001-\$75,000 4-\$75,001-\$100,000 5-\$100,001-\$250,000 *Additional Options Listed Below *Additional Options Listed Below
4. In the last 12 months have you spent at least one night in any of the following places? (DMNIGHT) If "Yes", select all that apply:	□ 0-No □ 1-Yes
(DMSHLTR1) A shelter for homeless persons.	
(DMSTRET1) On the street or in a public place not intended for sleeping (e.g., abandoned building, subway, or ca	ar).
(DMSRO1) In a welfare hotel or single room occupancy (SRO).	
(DMHLFWY1) In any emergency, temporary, or transitional housing program, or a halfway house.	
(DMSMELS1) Doubled up with others, in someone else's house/apartment.	
<ol> <li>Are you currently living in any of the places listed above?(DMLIVING)</li> <li>If "Yes", select all that apply:</li> </ol>	□ 0-No □ 1-Yes
(DMSHLTR2) A shelter for homeless persons.	
(DMSTRET2) On the street or in a public place not intended for sleeping (e.g., abandoned building, subway, or ca	ar).
(DMSRO2) In a welfare hotel or single room occupancy (SRO).	
(DMHLFWY2) In any emergency, temporary, or transitional housing program, or a halfway house.	
(DMSMELS2) Doubled up with others, in someone else's house/apartment.	
b. How many months have you lived there?(DMMONTHS)	1-Less than a month 2-1-2 months 3-3-4 months 4-5-6 months 5-More than 6 months
Comments:(DM1COMM)	

# Additional Selection Options for DM1

What has been your usual employment pattern in the past 12 months? 6-Retirement/disability 7-Unemployment 8-In controlled environment 9-Service (volunteer)

What is your combined household income? 6->\$250,000

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Web Version: 1.0; 5.03; 01-05-21

1	ED Visit Review (EDR)
Segment (PROTSEG): C //sit number (VISNO):	
Date of ED admission:(EDRASMDT)	(mm/dd/yyyy)
How was this patient identified?(ERPTID)	01-Screening by Emergency Department (ED) staff  02-Health quiz by research staff 03-Electronic health record (EHR) chief complaint 04-Emergency Department (ED) staff referral 99-Other
If *Other", specify:(ERPTIDSP)	¥
2. What was the chief complaint as written in the Emergency Department (ED) chart or ED provider notes?(ERCOMPL)	
What was the discharge diagnosis?(ERDSCDG)	
What are the ICD 10 code(s) for the discharge diagnosis?    a. Code 1:(ERICDCD)	
b. Code 2:(ERICDCD2)	
c. Code 3:(ERICDCD3)	
d. Code 4:(ERICDCD4)	
e. Code 5:(ERICDCD5)	
e. Code 5:(ERICDCD5)  f. Code 6:(ERICDCD6)	
g. Code 7:(ERICDCD7)	
h. Code 8:(ERICDCD8)	
i. Code 9:(ERICDCD9)	
j. Code 10:( <i>ERICDC10</i> )	
5. What was the date of discharge?(ERDISCDT)	(mm/dd/yyyy)
6. Did the patient come to the ED specifically for a referral to substance abuse treatment? (EREDREFR)	□ 0-No □ 1-Yes
7. Which RA consented patient and completed assessment forms?(ERRACNST)	01-SP 🛕
Which RA consented patient and completed assessment forms?(ERRACNST)	03-EC 04-MKL 05-EPR *Additional Options Listed Below  06-AM 07-DGa 08-DGr 09-KV 10-KW *Additional Options Listed Below
<ol> <li>Which RA consented patient and completed assessment forms?(ERRACNST)</li> </ol>	16-AR 17-BP 18-DE 19-HR 20-RH *Additional Options Listed Below
Which RA consented patient and completed assessment forms?(ERRACNST)	23-SG 24-CH 25-CM 26-TN 27-LW *Additional Options Listed Below
11. Who was the discharge attending?(ERDISATT)	01-Bayram, J.
11. YTID WAS DIE GISCHBIJER (ERDISAFF)	01-Bayram, J. 02-Bright, L 03-Catlett, C. 04-Chanmugam, A. 05-de Ramirez, S. *Additional Options Listed Below
Was an addiction related consult performed?(ERCONSUL)	□ 0-No □ 1-Yes
If "Yes", who performed the consult?(ERCONSPR)	01-Social work 02-Substance Use Counselor/Health Promotion Advocate (on-site hospital employee) 03-Recovery Coach/Peer Consult (not on-site hospital employee) 04-General psychiatrist 05-Addiction MD specialist *Additional Options Listed Below
3. Did the ED practitioner document that any of the following were provided:	
a. Brief intervention:(ERPRVBI)	□ 0-No □ 1-Yes
b. Advice:(ERPRVADV)	□ 0-No □ 1-Yes
c. Overdose education:(ERPRVODE)	□ 0-No □ 1-Yes

Date of PI review:(ERPISGDT)

<ol> <li>Were any of the following a. HIV:(ERHIVTST)</li> </ol>	tests performed:					Ο.	
b. Hepatitis C:(ERHCVT	ST)						1-Yes 1-Yes
					_ 0.10		
	medications administered in the		-	se?			
	^2 Medications Administered ^:	2 Medications Prescribed	^2 Medications Provided for Take Home Administration				
	No	Yes	No	Yes	No		Yes
a. Opioids:	(EROPIMED)		(EROPIRX)		(EROPITH)		
b. Benzodiazepines:	(ERBZOMED)		(ERBZORX)		(ERBZOTH)		
c. Methadone:	(ERMTDMED)		(ERMTDRX)		(ERMTDTH)		
d. Buprenorphine:	(ERBUPMED)		(ERBUPRX)		(ERBUPTH)		
e. Naltrexone:	(ERNALTMD)		(ERNALTRX)		(ERNALTTH)		
f. Naloxone:	(ERNALXMD)		(ERNALXRX)		(ERNALXTH)		
If a naloxone presc	cription was received, did the patie	ent receive a kit or a presc	ription?(ERKITRX)		☐ 1-Kit	□ 2.	2-Prescription
40 8:111		UD)	-				
	referral to opioid use disorder (Ol specific time and location?(ERRE		r)		☐ 0-No ☐ 0-No		1-Yes
If "Yes", answer the fo		,			□ 0-N0		1-165
b. Site name of the OUD	specific referral:(ERREFSIT)						
c. Location type of OUD	specific referral:(ERREFLOC)				1-Office-b 2-Opioid t 3-Residen 99-Other	reatm	ment program
If "Other", specify:(	ERLOCSP)						
17. Did the patient receive a	psychiatric evaluation during the	ED visit?(ERPSYCH)			O-No	□ 1	1-Yes
24 hours? (no induction of	d for ED-initiated buprenorphine a or prescription needed.)(EREVAL, what was noted in the discharge i	) -	for medication assisted treatmen	nt withir	0-No	□ 1	1-Yes
	ts/information regarding OUD ser				□ 1-		
	e., advice to go to specific place	without appointment) for C	OUD services:(ERINDREF)		□ 1-		
	o OUD:(ERNOOUD)				1		
If "Indirect referral",	, select the type of place: <i>(ERREF</i>	NOT)					atment program A ed provider
If "Other", specif	fy:(ERRFNTSP)						
Comments:(EDRCOMM)							
PI signature to indicate fo	orm review:(ERPISIGN)						

(mm/dd/yyyy)

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Additional Selection Options for EDR
Which RA consented patient and completed assessment forms?
21-BK
22-PU
33-GH
34-TM
54-RK
37-AH
55-RP
56-BM
45-KJ
46-SK
47-AE
48-48NA
48-48NA
Which RA consented patient and completed assessment forms?
11-BT
12-SR
13-NM
14-WR
15-AW
32-MB
38-BV
41-SV
42-FE
43-AL
57-57NA
58-58NA
59-59NA
60-60NA
61-61NA
61-61NA
62-62NA
63-63NA
64-64NA
65-65NA
Which RA consented patient and completed assessment forms?
65-65NA

Which RA consented patient and completed assessment forms?
35-DD
36-NQ
40-Aho
44-HRo
49-SRe
52-AV
53-Hry
72-72NA
73-73NA
74-74NA
75-75NA
76-76NA
77-77NA
78-78NA
79-79NA
80-80NA
80-80NA
Which RA consented patient and completed assessment forms?
39-DA
50-LK
51-RC
84-SM
85-85NA
86-86NA
87-87NA
88-88NA
99-99NA
90-99NA
91-91NA
92-92NA
93-93NA
94-94NA
95-95NA
Who was the discharge attending?
06-Dugas, A.
07-Ehmann, M.
08-Euster, C.
09-Fong, T.
10-Hansoti, B.
11-Hile, D.
12-Hile, L.
13-Hill, P.
14-Hill, T.
15-Hinson, J.
16-Hsu, E.
17-Jung, J.
18-Kane, E.
19-Kelen, G.
20-King, M.
21-Kirsch, T.
22-Kozen, J.
23-Levy, J.
23-Levy, J.
23-Levy, J.
24-Levy, M.
25-Margolis, A.
26-Millin, M.
27-Morton, M.
28-Omron, R.
29-Peterson, S.
30-Putman, S.
31-Qureshi, A.
32-Razzak, J.
33-Regan, L.
34-Rice, J.
33-Regan, L.
34-Rice, J.
35-Rothman, R.
36-Saheed, M.
37-Shah, S.
38-Shelton, E.
39-Stolbach, A.
40-Tang, N.
41-Vu, A.
42-Wilson, C.
43-Woltman, N.
41-Vu, A.
42-Wilson, C.
43-Woltman, N.
41-Abdelsamad, D.
45-Carmody, S.
46-Davis, M.
47-Dsouza, M.
48-Figueroa, S.
49-Ghazarian, S.
50-Haley, E.
51-Huntley, B.
52-Jackson, A.
53-Jokl, J.
54-Juhaszova, K.
55-Jones, T.
56-Lewis, A.
57-Masterson, M.
58-Milch, L.
59-Pomeroy, A.
60-Ridenour, P.
61-Roane, Y.
62-Robinson, S.
63-Soott, C.
64-Smith, T.
65-Steiner, L.
66-Tobar, M.
67-Updike, M.
```

If "Yes", who performed the consult? 99-Other

# ED Visits and Hospitalization (EDV)

Segment (PROTSEG): C Visit number (VISNO): ED visit hospitalization (EDHOSPDT): Document sequence number (SEQNUM):

# **ED Index Visit**

f. Code 6:(EDV6/CD)
g. Code 7:(EDV7/CD)
h. Code 8:(EDV8/CD)
i. Code 9:(EDV9/CD)
j. Code 10:(EDV10/CD)
Comments:(EDVCOMM)

	ED Index Visit	
	ED enrollment date:(EDEDENRL)	
	Chief complaint:(EDICOMPL)	
١.	Discharge date:(EDIDISDT)	
ŀ.	Discharge diagnosis:(EDIDISDG)	
j.	ICD 10 code(s) for the discharge diagnosis:	
	a. Code 1:(EDIICD10)	
	b. Code 2:(ED2ICD10)	
	c. Code 3:(ED3/CD10)	
	d. Code 4:(ED4ICD10)	
	e. Code 5:(ED5/CD10)	
	f. Code 6:(ED6/CD10)	
	g. Code 7:(ED7/CD10)	
	h. Code 8:(ED8/CD10)	
	i. Code 9:(ED9/CD10)	
	j. Code 10:(ED10ICD)	
	ED Visit or Hospitalization After the ED Index Visit	
i.	Has the patient visited the ED or been hospitalized between the screening and follow-up visits?(EDVVISIT)	
	ED visit or hospitalization:(EDVHOSP)	
١.	Chief complaint:(EDVCOMPL)	
).	Discharge date:(EDVDISDT)	
١.	Discharge diagnosis:(EDVDISDG)	
	ICD 10 code(s) for the discharge diagnosis:	
	a. Code 1:(EDVICD10)	
	b. Code 2:(EDV2ICD)	
	c. Code 3:(EDV3/CD)	
	d. Code 4:(EDV4/CD)	
	e. Code 5:(EDV5ICD)	

	(IIIII/dd/yyyy)	
	(mm/dd/yyyy)	
	(	
□ 0-No □ 1-Y		
U 0-N0 U 1-Y	es e e e e e e e e e e e e e e e e e e	
	01-Hospitalization	
	01-Hospitalization	
	01-Hospitalization	

/

Web Version: 1.0; 6.04; 05-28-19

# Additional Selection Options for EDV

Additional Selection Options for ED

Document sequence number (SEQNUM) (key field):
01-1
02-2
03-3
04-4
05-5
06-6
07-7
08-8
09-9
10-10
11-11
12-12
13-13
14-14
15-15
16-16
17-17
18-18
19-19
20-20

EQ-5D-3L (EQD)

Web Version: 1.0; 3.00; 03-28-18

Segment (PROTSEG): C Visit number (VISNO):



## **Health Questionnaire**

 $@\ EuroQol\ Research\ Foundation.\ EQ-5D^{\rm TM}\ is\ a\ trade\ mark\ of\ the\ EuroQol\ Research\ Foundation.$ 

Under each heading, please tap the ONE box that best describes your health TODAY.

Mobility (EQ5MBTLY) Self-Care

(EQ5SLFCR)

Usual Activities (e.g. work, study, housework, family, or leisure activities)

Pain / Discomfort (EQ5PAIND)

Anxiety / Depression

(EQ5ANXDE)

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- We would like to know how good or bad your health is TODAY.
  This scale is numbered 0 to 100.
  100 means the best health you can imagine.
  O means the worst health you can imagine.
  Please tap on the scale to indicate how your health is TODAY.

YOUR HEALTH TODAY*(EQ5HLTTD)* 

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☐ MB1-I have no problems in walking about ☐ MB2-I have some problems in walking about ☐ MB3-I am confined to bed
SC1-I have no problems with self-care SC2-I have some problems washing or dressing myself SC3-I am unable to wash or dress myself
UA1-I have no problems with performing my usual activities UA2-I have some problems with performing my usual activities UA3-I am unable to perform my usual activities
□ PD1-I have no pain or discomfort □ PD2-I have moderate pain or discomfort □ PD3-I have extreme pain or discomfort
□ AD1-I am not anxious or depressed □ AD2-I am moderately anxious or depressed □ AD3-I am extremely anxious or depressed
(xxx) The best health you can imagine The worst health you can imagine

Segment (PROTSEG): C Visit number (VISNO):

## **NIDA Clinical Trials Network**

## **Engagement in Treatment: Facility (ETF)**

Facility name (FACPRLC): Date of assessment:(ETDATE) (mm/dd/yyyy) 1-Office-based provider 1. What type of Provider/Program is this?(ETPROGRM) 2-Opioid treatment program 3-Residential program 99-Other If "Other", specify:(ETPROGSP) On [Enter 30day Target Date] was this patient engaged in a program at your facility or being treated at your office for their opioid use disorder?(ETENGAGE) ☐ 0-No ☐ 1-Yes If "Yes", review and answer the following questions: a. Indicate the type(s) of treatment they were receiving for their opioid use disorder on [Enter 30day Target Date]: No Methadone: (ETMTD) Buprenorphine: (ETBUP) Naltrexone: (ETNAL) Short-term detoxification: (ETSTDETX) Inpatient: (ETINPT) Outpatient counseling: (ЕТОТРТ) Other, specify:(ETOTRSP) (ETOTHER) b. On [Enter 30day Target Date], how would you categorize the level of treatment received by this patient? (ETCATGTR) 0-No care received 1-Level I: Outpatient treatment 2-Level II: Intensive outpatient treatment (including partial hospitalization) 3-Level III: Residential/inpatient services 4-Level IV: Medically managed intensive inpatient treatment \*Additional Options Listed Below If "Other", specify:(ETCATSP) c. What was the date of their admission into your program or, if office-based, when did their care begin? (ETADMSDT) (mm/dd/yyyy) d. Was the patient discharged?(ETDISCH) □ 0-No □ 1-Yes If "Yes", date of discharge from your care:(ETDSCDT) (mm/dd/yyyy) Comments:(ETFCOMM)

1

Web Version: 1.0: 3.02: 09-23-19

# Additional Selection Options for ETF

On [Enter 30day Target Date], how would you categorize the level of treatment received by this patient? 99-Other

Segment (PROTSEG): C Visit number (VISNO):

Comments:(ETPCOMM)

### **NIDA Clinical Trials Network**

### Engagement in Treatment: Patient (ETP)

The next questions ask about the medical care you have received for an opioid use disorder on [insert 30day Target Date]. 1. On [insert 30day Target Date] are/were you receiving treatment for opioid use disorder?(ETMEDTRT) ☐ 0-No ☐ 1-Yes a. ^2Where are/were you receiving this treatment? Program/Provider #2 Program/Provider #1 Program/Provider #3 (ETPRLC03) (ETPRLC01) (ETPRLC02) c. @8What type(s) of treatment Methadone: (ETMETH1) 0-No 1-Yes (ETMETH2) 0-No 1-Yes (ETMETH3) 0-No 1-Yes or treatment are/were you receiving? Only include formal treatment (e.g., do not include NA, AA, or faith-based). Buprenorphine: (ETBUP1) 0-No 1-Yes (ETBUP3) 🗆 0-No 🗆 1-Yes (ETBUP2) 0-No 1-Yes Naltrexone: (ETNALTR1) 0-No 1-Yes (ETNALTR2) 0-No 1-Yes (ETNALTR3) 0-No 1-Yes Short-term detoxification: (ETDETOX1) 0-No 1-Yes (ETDETOX2) 0-No 1-Yes (ETDETOX3) 0-No 1-Yes Inpatient: (ETINPAT1) 0-No 1-Yes (ETINPAT2) 0-No 1-Yes (ETINPAT3) 0-No 1-Yes Outpatient counseling: (ETOTPAT1) □ 0-No □ 1-Yes (ETOTPAT2) 0-No 1-Yes (ETOTPAT3) □ 0-No □ 1-Yes Other: (ETOTHER1) 

0-No 

1-Yes (ETOTHER2) 

0-No 

1-Yes (ETOTHER3) 🗆 0-No 🗆 1-Yes If "Other", (ETOTHSP1) (ETOTHSP2) (ETOTHSP3) specify: d. ^2Who is/was (ETCOCLI1) (ETCOCLI2) (ETCOCLI3) your counselor/clinician? f. ^2ls/was this service covered by: 1-Insurance 
2-Self-pay 1-Insurance 🔺 1-Insurance 🔺 2-Self-pay 2-Self-pay 3-No-cost 3-No-cost 3-No-cost (ETCOVRD2) (ETCOVRD1) (ETCOVRD3) 2. On [insert 30day Target Date] are/were you:(ETL/VE) 1-Living in the community 2-Incarcerated 3-An inpatient (e.g., overnight in hospital, substance abuse treatment) 99-Other If "Other", specify:(ETLIVESP)

Web Version: 1.0; 3.01; 09-23-19

# **NIDA Clinical Trials Network**

0069C	(ENR)
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	Date eligibility confirmed:(STARTDT)		(mm/dd/yyyy)			
	Patient date and time to bed in Emergency Department:(RSEDDT)	Date:		(mm/dd/yyyy)	(R5EDTM) Time:	(hh:mm)
	Inclusion Criteria					
	In order to meet eligibility ALL Inclusion answers must be "Yes".					
1	Participant is 18 years of age or older:(R5PTAGE)	□ 0-No	1-Yes	☐ 97-Unknown		
2	Participant presented to the Emergency Department during study screening hours:(R5SCHOUR)	□ 0-No	1-Yes	97-Unknown		
3	Participant meets DSM-5 diagnostic criteria for moderate to severe opioid use disorder:(R5DSMOUD)	□ 0-No	1-Yes	97-Unknown		
4	Participant has a urine toxicology test, taken prior to any Emergency Department provided opioid medication, that is positive for opioids:(R5URIOPI)	☐ 0-No	1-Yes	☐ 97-Unknown		
	Exclusion Criteria					
	In order to meet eligibility ALL Exclusion answers must be "No".					
1	Participant has a medical or psychiatric condition that requires hospitalization at the index Emergency Department visit: (R5HOSPTL)	O-No	☐ 1-Yes	☐ 97-Unknown		
2	Participant is actively suicidal or severely cognitively impaired:(R5SUICDE)	O-No	1-Yes	97-Unknown		
3	Participant presents from extended care facility (e.g., skilled nursing facility):(R5EXCARE)	O-No	1-Yes	☐ 97-Unknown		
4	Participant requires continued prescription opioids for a pain condition:(R5RXOPI)	□ 0-No	1-Yes	☐ 97-Unknown		
5	Participant is a prisoner or is in police custody at the time of index Emergency Department visit: (R5PRISON)	☐ 0-No	1-Yes	☐ 97-Unknown		
6	Participant currently has (past 30 days) enrolled in formal addiction treatment, including by court order:(R5ADDTRT)	O-No	1-Yes	☐ 97-Unknown		
7	Participant is unable to provide reliable locator information including 2 contact numbers:(R5LOCATE)	☐ 0-No	1-Yes	☐ 97-Unknown		
8	Participant is unwilling to follow study procedures (e.g., unwilling to provide permission to contact referral provider/program or to return for 30-day assessment):(R5UNSTDY)	O-No	1-Yes	☐ 97-Unknown		
9	Participant has prior participation in the current study:(R5PRIOR)	O-No	1-Yes	☐ 97-Unknown		
10	Participant is not able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study:(R5ENGLSH)	O-No	1-Yes	☐ 97-Unknown		
	Eligibility for Enrollment					
1	Is the participant eligible for the study?(R5ELGSTY)	□ 0-No	1-Yes			
2	Will the participant be enrolled?(R5BEENR)	☐ 0-No	1-Yes			
	If "No", specify:(R5NENRSP)		or to comple	ticipation a etion		
	If "Other", specify:(R507JGSP)					
	Comments:(R5COMM)					

Web Version: 1.0; 1.01; 01-07-21

## Timeline Followback Page 2 (F69)

TFB week start date (TFWKSTDT):

h.							
Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	(TLDATE1)	(TLDATE2)	(TLDATE3)	(TLDATE4)	(TLDATE5)	(TLDATE6)	(TLDATE7)
Have any pain relievers, pain medications, sedatives, alcohol, methamphetamine, cocaine, heroin, or other illicit substances been used on this day?	(TLSUBAL1) □ 0-No □ 1-Yes	(TLSUBAL2) 🗆 0-No 🗆 1-Yes	(TLSUBAL3) □ 0-No □ 1-Yes	(TLSUBAL4) 0-No 1-Yes	(TLSUBAL5) 0-No 1-Yes	(TLSUBAL6) 0-No 1-Yes	(TLSUBAL7) 🗆 0-No 🗆 1-Yes
2. Pentazocine (Talwin):							
Route:	(TLPENZ1) 0-00-No use	(TLPENZ2) 0-00-No use	(TLPENZ3) 0-00-No use	(TLPENZ4) 0-00-No use	(TLPENZ5) 0-00-No use	(TLPENZ6) 0-00-No use	(TLPENZ7) 0-00-No use
	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral
	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking
	4-04-Non-IV Injection	4-04-Non-IV Injection					
	*Additional Options Listed Below	*Additional Options Listed Below					
Prescribed:	(TLPPENZ1) O-No 1-Yes	(TLPPENZ2) 0-No 1-Yes	(TLPPENZ3) 0-No 1-Yes	(TLPPENZ4) 0-No 1-Yes	(TLPPENZ5) 0-No 1-Yes	(TLPPENZ6) 0-No 1-Yes	(TLPPENZ7) 0-No 1-Yes
# Times Used Each Day:	(TLTPENZ1) (xxx)	(TLTPENZ2) (xxx)	(TLTPENZ3) (xxx)	(TLTPENZ4) (xxx)	(TLTPENZ5) (xxx)	(TLTPENZ6) (xxx)	(TLTPENZ7) (xxx)
3. Codeine:							
Route:	(TLCODE1) 0-00-No use	(TLCODE2) 0-00-No use	(TLCODE3) 0-00-No use	(TLCODE4) 0-00-No use	(TLCODE5) 0-00-No use	(TLCODE6) 0-00-No use	(TLCODE7) 0-00-No use
	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral
	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking
	4-04-Non-IV Injection	4-04-Non-IV Injection					
	*Additional Options Listed Below	*Additional Options Listed Below					
Prescribed:	(TLPCODE1) 0-No 1-Yes	(TLPCODE2) 0-No 1-Yes	(TLPCODE3) 0-No 1-Yes	(TLPCODE4) 0-No 1-Yes	(TLPCODE5) 0-No 1-Yes	(TLPCODE6) 0-No 1-Yes	(TLPCODE7) 0-No 1-Yes
# Times Used Each Day:	(TLTCODE1) (xxx)	(TLTCODE2) (xxx)	(TLTCODE3) (xxx)	(TLTCODE4) (xxx)	(TLTCODE5) (xxx)	(TLTCODE6) (xxx)	(TLTCODE7) (xxx)
4. Benzodiazepines (Valium, Serpax, Ativan, Xanax, Librium, Rohypnol):							
Route:	(TLBZO1) 0-00-No use	(TLBZO2) 0-00-No use	(TLBZO3) 0-00-No use	(TLBZO4) 0-00-No use	(TLBZO5) 0-00-No use	(TLBZO6) 0-00-No use	(TLBZO7) 0-00-No use
	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral
	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking
	4-04-Non-IV Injection	4-04-Non-IV Injection					
	*Additional Options Listed Below	*Additional Options Listed Below					
Prescribed:	(TLPBZO1) □ 0-No □ 1-Yes	(TLPBZO2)	(TLPBZO3) 0-No 1-Yes	(TLPBZO4)	(TLPBZO5)	(TLPBZO6)	(TLPBZO7) □ 0-No □ 1-Yes
# Times Used Each Day:	(TLTBZO1) (xxx)	(TLTBZO2) (xxx)	(TLTBZO3) (xxx)	(TLTBZO4) (xxx)	(TLTBZO5) (xxx)	(TLTBZO6) (xxx)	(TLTBZO7) (xxx)
5. Methamphetamine (speed, crystal meth, ice):							
Route:	(TLMET1) 0-00-No use	(TLMET2) 0-00-No use	(TLMET3) 0-00-No use	(TLMET4) 0-00-No use	(TLMET5) 0-00-No use	(TLMET6) 0-00-No use	(TLMET7) 0-00-No use
	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral	1-01-Oral
	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking	2-02-Nasal 3-03-Smoking
	4-04-Non-IV Injection *Additional Options Listed Below	4-04-Non-IV Injection *Additional Options Listed Below					
			v	v	v		
Prescribed:	(TLPMET1) 0-No 1-Yes	(TLPMET2) 0-No 1-Yes	(TLPMET3) 0-No 1-Yes	(TLPMET4) 0-No 1-Yes	(TLPMET5)	(TLPMET6) 0-No 1-Yes	(TLPMET7) 0-No 1-Yes
# Times Used Each Day:	(TLTMET1) (xxx)	(TLTMET2) (xxx)	(TLTMET3) (xxx)	(TLTMET4) (xxx)	(TLTMET5) (xxx)	(TLTMET6) (xxx)	(TLTMET7) (xxx)
6. Cocaine (coke, crack):							
Route:	(TLCOC1) 0-00-No use	(TLCOC2) 0-00-No use	(TLCOC3) 0-00-No use	(TLCOC4) 0-00-No use	(TLCOC5) 0-00-No use	(TLCOC6) 0-00-No use	(TLCOC7) 0-00-No use
	1-01-Oral 2-02-Nasal	1-01-Oral 2-02-Nasal	1-01-Oral 2-02-Nasal	1-01-Oral 2-02-Nasal	1-01-Oral 2-02-Nasal	1-01-Oral 2-02-Nasal	1-01-Oral 2-02-Nasal
	3-03-Smoking	3-03-Smoking	3-03-Smoking	3-03-Smoking	3-03-Smoking	3-03-Smoking	3-03-Smoking
	4-04-Non-IV Injection *Additional Options Listed Below	4-04-Non-IV Injection *Additional Options Listed Below					
	, add solid Options Elsted Below	, additional options ballow	, additional options ballow	v v v v v v v v v v v v v v v v v v v	, additional Options Elated Below	, identification of the property of the proper	v v v
# Times Used Each Day:	(TLTCOC1) (xxx)	(TLTCOC2) (xxx)	(TLTCOC3) (xxx)	(TLTCOC4) (xxx)	(TLTCOC5) (xxx)	(TLTCOC6) (xxx)	(TLTCOC7) (xxx)
7. Alcohol:							
# Times Used Each Day:	(TLTALCH1) (XXX)	(TLTALCH2) (xxx)	(TLTALCH3) (xxx)	(TLTALCH4) (XXX)	(TLTALCH5) (xxx)	(TLTALCH6) (xxx)	(TLTALCH7) (xxx)
8. Cannabis (marijuana, pot, grass, hash):							/

Web Version: 1.0; 2.00; 09-25-17

Comments:(TFBCOMM)

Route:	(7LTHC1) (0-00-No use 1-01-Oral 2-02-Nasal 3-33-Smoking 4-04-Non-IV Injection "Additional Options Listed Below	(TLTHC2) (0-00-No use 1-01-0ral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection "Additional Options Listed Below	(TLTHC3) [0-00-No use	(TLTHC4) (0-00-No use 1-01-0ral 2-02-Nasal 3-33-Smoking 4-04-Non-IV Injection "Additional Options Listed Below	(TLTHC5) [0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection "Additional Options Listed Below	(TLTHC6) (0-00-No use 1-01-0ral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection "Additional Options Listed Below	(TLTHC7) (D-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection "Additional Options Listed Below "
Prescribed:	(TLPTHC1) 0-No 1-Yes	(TLPTHC2) 0-No 1-Yes	(TLPTHC3) 0-No 1-Yes	(TLPTHC4) 0-No 1-Yes	(TLPTHC5) 0-No 1-Yes	(TLPTHC6) 0-No 1-Yes	(TLPTHC7) 0-No 1-Yes
# Times Used Each Day:	(TLTTHC1) (xxx)	(TLTTHC2) (xxx)	(TLTTHC3) (xxx)	(TLTTHC4) (xxx)	(TLTTHC5) (xxx)	(TLTTHC6) (xxx)	(TLTTHC7) (xxx)
9. Other drug 1 use:							
Route:	(TLOT11) 0-00-No use 1-01-Oral 2-02-Nasal 3-33-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT12) (0-00-No use 1-01-0ral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(7LO713)  0-00-No use 1-01-0ral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT14) (0-00-No use 1-01-0ral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT15) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT16) (0-00-No use	(TLOT17) (0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPOT11)	(TLPOT12)	(TLPOT13) 0-No 1-Yes	(TLPOT14)	(TLPOT15)	(TLPOT16) 0-No 1-Yes	(TLPOT17)
# Times Used Each Day:	(TLTOT11) (xxx)	(TLTOT12) (xxx)	(TLTOT13) (xxx)	(TLTOT14) (xxx)	(TLTOT15) (xxx)	(TLTOT16) (xxx)	(TLTOT17) (xxx)
Specify other drug 1:	(TLOTSP11)	(TLOTSP12)	(TLOTSP13)	(TLOTSP14)	(TLOTSP15)	(TLOTSP16)	(TLOTSP17)
10. Other drug 2 use:							
Route:	(7LO721) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection "Additional Options Listed Below	(TLOT22) (0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection "Additional Options Listed Below	(TLOT23) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection "Additional Options Listed Below	(7LOT24) (0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection "Additional Options Listed Below	(7LO725) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-S-moking 4-04-Non-IV Injection "Additional Options Listed Below	(7LO726) (0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection "Additional Options Listed Below	(7LOT27) (0-00-No use 1-01-07al 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPOT21)	(TLPOT22) □ 0-No □ 1-Yes	(TLPOT23) 🗆 0-No 🗆 1-Yes	(TLPOT24)	(TLPOT25) □ 0-No □ 1-Yes	(TLPOT26)	(TLPOT27)
# Times Used Each Day:	(TLTOT21) (xxx)	(TLTOT22) (xxx)	(TLTOT23) (xxx)	(TLTOT24) (xxx)	(TLTOT25) (xxx)	(TLTOT26) (xxx)	(TLTOT27) (xxx)
Specify other drug 2:	(TLOTSP21)	(TLOTSP22)	(TLOTSP23)	(TLOTSP24)	(TLOTSP25)	(TLOTSP26)	(TLOTSP27)

# **Additional Selection Options for F69**

**D1 pentazocine** 5-05-IV Injection 99-99-Other

# Follow-Up Visit Scheduling (FVT)

Segment (PROTSEG): C Visit number (VISNO):

Please schedule the follow up visit date and time with this participant. The target date range for the 30 day follow-up visit is from j\_edate+30 to j\_edate+44

Date of 30 day follow-up visit:(FVAPPTDT)	(mm/dd/yyyy)
Appointment time:(FVAPPTTM)	(hh:mm) (24-hour time)
Comments:(FVTCOMM)	

Web Version: 1.0; 2.01; 07-02-18

Health Services Utilization Page 1: Inpatient (HS1)

Web Version: 1.0; 1.01; 10-03-1
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Segment (PRUISEG):	C
Visit number (VISNO):	

Now I would like to review, in detail, any facilities in which you have been hospitalized overnight for any reason (physical, emotional, or substance abuse) during the past 30 days. Please include residential detox facilities but do not include sober houses or halfway house stays.

Were any inpatient services used in the past 30 days?(HS1SU)

If "Yes", how many inpatient facilities were utilized in the past 30 days?(HS1FAC)

(xx) facilities

## Health Services Utilization Page 1: Outpatient (HS2)

Web Version: 1.0; 1.01; 08-20-18

Segment (PROTSEG): C Visit number (VISNO):

Next, I want to ask you about when you were an outpatient. Please include regular doctor visits, visits to Emergency Departments/Rooms (ED), and any treatment centers (e.g., methadone maintenance centers). Let's review, in detail, each practitioner or community service you received as an outpatient for any reason (physical, emotional, or substance abuse) during the past 30 days.

Next, I want to ask you about when you were an outpatient. Please include regular doctor visits, visits to Emergency Departments/Rooms (ED), not including ED enrollment visit, and any treatment centers (e.g., methadone maintenance centers). Let's review, in detail, each practitioner or community service you received as an outpatient for any reason (physical, emotional, or substance abuse) during the past 30 days.

ere any outpatient services used in the past 30 days? (13230)		☐ 1-Yes
If "Yes", how many outpatient facilities were utilized in the past 30 days?(HS2FAC)		(xx) facilitie
ere any outpatient services used in the 30 days prior to the follow up visit target date? (HS2SU)	O-No	1-Yes
If "Yes", how many outpatient facilities were utilized in the 30 days prior to the follow up visit target date? (HS2FAC)		(xx) facilitie

Health Services Utilization: Inpatient (HSI)

☐ 1-Insurance ☐ 2-Self-pay ☐ 3-No-cost

Segment (PROTSEG): C Visit number (VISNO): Facility name (FACPRLC): Sequence number (SEQNUM2):

Comments:(HSICOMM)

Please describe your stay including the type of inpatient service that was provided. Provider code:
 Note to RA: If patient endorses 'Inpatient substance abuse treatment (residential)', then refer back to eligibility criteria. 1-Medical hospital 2-Psychiatric hospital (HSPRCODE) 3-Inpatient substance abuse treatment (residential)
4-Skilled nursing/extended care facility 99-Other inpatient facility If "Other inpatient facility", specify:(HSOTHISP) 1-Medical/surgical
 2-Psychiatric (non-substance abuse)
 3-Substance abuse
 4-Psychiatric and substance abuse Service type: Note to RA: If patient endorses 'Substance abuse' or 'Psychiatric and substance abuse', then refer back to eligibility criteria. (HSSRTYPE) 3. What was the reason for the hospitalization?(HSHSPRSN) A. Number of nights stayed this visit:
Include all days in the facility, including days arising from a stay which began prior to the start of the 30 DAY period.
(HSNITNUM)

5. Number of admissions in PAST 30 days:
Include any admission during the 30 DAYS (e.g., if a patient was hospitalized continuously there would have been no admissions in 30 DAYS). Consider transfers as new admissions if they involve a different kind of service (i.e., service type).
(HSSDMNUM)

6. Visit(s) paid for by:(HSVSPAID) (xxx)

Web Version: 1.0: 2.04: 10-03-18

# **Additional Selection Options for HSI**

Sequence number (SEQNUM2) (key field): 01-1 02-2 03-3 04-4 05-5 06-6 07-7 08-8 09-9 10-10

Segment (PROTSEG): C Visit number (VISNO):

## **NIDA Clinical Trials Network**

## **Health Services Utilization: Outpatient (HSO)**

Facility name (FACPRLC): Please describe the type of outpatient service that was provided and about your stay. 1. Provider code:(HSPVCODE) 1-Hospital-based clinic 2-Federally-qualified (community) health center 3-Private doctor's office 4-Emergency department 5-Urgent care center/walk-in facility \*Additional Options Listed Below If "Other", specify:(HSPVOTSP) 2. Service type: (HSSERVTP) 1-Medical/surgical 2-Psychiatric (non-substance abuse) 3-Substance abuse 4-Psychiatric and substance abuse 3. Provider type:(HSPVTYPE) 1-Doctor 2-Nurse 3-Nurse practitioner 4-Physician's Assistant (PA) 5-Chiropractor \*Additional Options Listed Below If "Other", specify:(HSPVOTH) 4. Number of visits in PAST 30 days:(HSNUMVIS) (xx) 5. Number of visits in the 30 days prior to your follow up visit target date:(HSNUMVIS) (xx) 6. Average minutes per visit: (xxxx) Include time spent with the provider (HSAVGMIN) 7. Visit(s) paid for by:(HSPAIDBY) ☐ 1-Insurance ☐ 2-Self-pay ☐ 3-No-cost 8. Medications received/amount in the past 30 days: Include substance abuse medications Medications received/amount in the 30 days prior to your follow up visit target date. Include substance abuse medications. Number of Days a. ^2Methadone: (HSMETHAD) 0-No 1-Yes (HSMETDAY) (xx) b. ^2Buprenorphine: (HSBUPREN) □ 0-No □ 1-Yes Oral: (HSBUPORL) 0-No 1-Yes (HSBPORDY) (xx) @2Implant: (HSBUPIMP) 0-No 1-Yes (HSBPIMDY) Implant date:(HSIMPDT) (xx) (mm/dd/yyyy) Removal date:(HSREMDT) (mm/dd/vvvv) Other (HSBUPOT) O-No 1-Yes (HSBPOTDY) (xx) c. ^2Naltrexone: (HSXRNTX) 0-No 1-Yes Oral: (HSNALORL) 0-No 1-Yes (HSNAORDY) Injectable: (HSNALINJ) 🗆 0-No 🗆 1-Yes Injection date:(HSINJDT) (mm/dd/yyyy) Date of second injection:(HSINJ2DT) (mm/dd/yyyy) Other: (HSNALOT) O-No 1-Yes (HSNAOTDY) d. ^2Naloxone (Narcan): (HSNARCAN) 0-No 1-Yes Number of doses:(HSNLNDOS) e. ^2Other medication: (HSOTHER) 0-No 1-Yes ^2Specify medication:(HSOTHSP) (HSOTHDY) Comments:(HSOCOMM)

Web Version: 1.0: 2.03: 09-25-19

# **Additional Selection Options for HSO**

Provider code: 6-Day surgery 7-Opioid treatment program 99-Other

Provider type: 6-Dentist 7-Counselor/psychologist 8-Self-help (e.g., NA, AA) 99-Other

H	Health Status (HST)
Segment (PROTSEG): C	Web Version: 1.0; 2.00; 04-11-18
Visit number (VISNO):	
Did you come to the Emergency Department today primarily to receive treatment or a referral for your opioid use? (HSEDRSN)	□ 0-No □ 1-Yes
Do you have a medical care provider whom you usually see?(HSMEDPRO)	□ 0-No □ 1-Yes
3. Where do you usually or most often go for medical care?(HSMEDLOC)	1-Hospital-based clinic 2-Federally-qualified (community) health center 3-Private doctor's office 4-Emergency department 5-Urgent care center/walk in facility *Additional Options Listed Below
If "Other", specify:(HSLOCSP)	
4. Do you know your HIV status?(HSKNOHIV)	□ 0-No □ 1-Yes □ 2-Never tested
If "Yes", what is your HIV status?(HSSTAHIV)	O-Negative 1-Positive
Do you know your Hepatitis C status?(HSKNOHEP)	0-No 1-Yes 2-Never tested
If "Yes", what is your Hepatitis C status?(HSSTAHEP)	O-Negative 1-Positive
	o-regaine
6. How many <b>times</b> have you hit up (i.e., injected yourself with any drugs or were injected by someone else) in the last	0-No times
month?(HSHITUP)	1-Once 2-More than once 3-Once a day 4-2-3 times a day 5-More than 3 times a day
7. How many times in the last month have you used a needle after someone else had already used it? Please include the number of times you used a needle after your partner in addition to the number of times you used a needle after others. (HSYOUAFT)	O-No times 1-One time 2-Two times 3-3-5 times 4-6-10 times 5-More than 10 times
8. How many <b>different</b> people (including your partner) have used a needle <b>before</b> you in the last month?(HSPPLBEF)	0-None 1-One person 2-Two people 3-3-5 people 4-6-10 people 5-More than 10 people
9. How many <b>times</b> in the last month has <b>someone else</b> used a needle <b>after</b> you used it?(HSPPLAFT)	O-No times 1-One time 2-Two times 3-3-5 times 4-6-10 times 5-More than 10 times
10. How <b>often</b> , in the last month, have you cleaned needles before re-using them?(HSCLNEED)	0-Doesn't re-use  1-Every time 2-Often 3-Sometimes 4-Rarely 5-Never
11. Before using needles again, how <b>often</b> in the last month did you use bleach to clean them?(HSCLBLEC)	0-Doesn't re-use  1-Every time 2-Often 3-Sometimes 4-Rarely 5-Never
Sexual Behavior Section	
12. How many <b>people</b> , including any regular partners, casual acquaintances and clients, have you had sex with in the last month?(HSPPLSEX)	0-None 1-One person 2-Two people 3-3-5 people 4-6-10 people 5-More than 10 people
13. How <b>often</b> , in the last month, have you used condoms when having sex with your <b>regular</b> partner(s)?(HSCONREG)	O-No regular partners / No penetrative sex  1-Every time 2-Often 3-Sometimes 4-Rarely 5-Never
14. How <b>often</b> , in the last month, have you used condoms when you had sex with <b>casual</b> partners (acquaintances)? (HSCONCAS)	0-No casual partners / No penetrative sex

<sup>15.</sup> How often, in the last month, have you used condoms when you have been paid for sex with money or drugs or when you have paid for sex with money or drugs?(HSCONPAD)

	0-No paid sex / No penetrative sex A 1-Every time 2-Often 3-Sometimes 4-Rarely 5-Never					
How many <b>times</b> have you had anal sex in the last month?(HSANALSX)	0-No times 1-One time 2-Two times 3-3-5 times 4-6-10 times 5-More than 10 times					
fow <b>often</b> have you used condoms during anal sex in the last month?(HSCONANL)	0-No regular partners / No penetrative sex 1-Every time 2-Often 3-Sometimes 4-Rarely 5-Never					
Pain Section						
Please use the range of 0 to 10 to answer the following questions.  Vhat number best describes your pain on average in the past week?(HSPAINAV)	(0.1)					
What number best describes how, during the past week, pain has interfered with your enjoyment of life?(HSENJOY)		(0 = No pain, 10 = Pain as bad as you can imagine)  (0 = Pain has not interfered at all, 10 = Pain has interfered extremely)				
What number best describes how, during the past week, pain has interfered with your general activity?(HSACTVTY)	(0 = Pain has not interfered at all,		• • • • • • • • • • • • • • • • • • • •			
Psychological Section						
n your lifetime, have you ever been treated for any psychological or emotional problems in a hospital or inpatient setting HSHOSP)	9? 🗆 0-No 🗆 1-Yes					
n your lifetime, have you ever been treated for any psychological or emotional problems as an outpatient/private patien HSOUTPT)	t?					
The past 30 days, have you been treated for any psychological or emotional problems with counseling or medication? HSCNMED)	□ 0-No □ 1-Yes					
24. Over the last 2 weeks, how often have you been bothered by any of the following problems?		Not at All	Several Days	More Than Half the Days	Nearly Every Day	
a. Little interest or pleasure in doing things:		(HSINTPL)				
b. Feeling down, depressed, or hopeless:		(HSDEPR)				
c. Trouble falling or staying asleep, or sleeping too much:		(HSSLEEP)				
d. Feeling tired or having little energy:		(HSTIRED)				
e. Poor appetite or overeating:		(HSEAT)				
f. Feeling bad about yourself-or that you are a failure or have let yourself or your family down:		(HSFAIL)				
g. Trouble concentrating on things, such as reading the newspaper or watching television:		(HSCONCEN)				
h. Moving or speaking so slowly that other people could have noticed. Or the opposite-being so fidgety or restless that	at you have been moving around a lot more than usual:	(HSMOVE)				
i. Thoughts that you would be better off dead, or of hurting yourself in some way:		(HSDEAD)				
tow difficult have these problems made it for you to do your work, take care of things at home, or get along with other eople?(HSDIFFC)	0-Not difficult at all 1-Somewhat difficult 2-Very difficult 3-Extremely difficult					

# **Additional Selection Options for HST**

Where do you usually or most often go for medical care? 6-No place 99-Other

## **Healthcare Visit Logistics (HVL)**

Segment (PROTSEG): C Visit number (VISNO):

Please answer the following questions about the time it takes to travel to your usual healthcare provider. If you are unsure about this information, give your best estimate.

About how many miles do you travel ONE WAY to get to your usual health care provider (e.g., medical doctor)?
 (If you have more than one usual provider, choose one.)(HVDISTSP)

2. About how long does it typically take to travel **ONE WAY** to your provider?(HVTMHRSP)

Comments:(HVLCOMM)

Hours:	(xx) (HVTMMNSP)Minutes:	(xx)
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Web Version: 1.0; 1.01; 05-23-17

#### Segment (PROTSEG): C Visit number (VISNO):

Reason for missed visit:(MVREASON)

If "Other", specify:(MVOTHRSP)

Comments:(MVFCOMM)

## Missed Visit (MVF)

1-Participant failed to return to site and unable to contact 2-Participant unable to attend visit (e.g., no childcare, transportation, sch 3-Participant on vacation 4-Participant illness 5-Participant in hospital, in-patient, or residential treatment *Additional Options Listed Below	edule conflict)	•
		₩

Web Version: 1.0; 1.01; 07-10-17

## Additional Selection Options for MVF

Reason for missed visit: 6-Participant moved from area 7-Participant incarcerated 8-Site closed 9-Participant withdrew consent 10-Participant deceased 99-Other

Enter death information on this form only if it has returned from the National Death Index (NDI) submission.

2. 3.

# NIDA Clinical Trials Network

## National Death Index (NDI)

Web Version: 1.0; 1.00; 05-11-20

Is this record reported as an exact match?(NDEXTMCH)	□ 0-No □ 1-Yes	
Date of death per NDI:(NDDTHDT)	(mm/dd/yyyy)	
NDI primary cause of death:(NDNDICOD)		
Is there any additional information provided concerning secondary cause of death or other contributing factors?(NDADDINF)	□ 0-No □ 1-Yes	
a. NDI secondary cause of death, if applicable:(NDNDISEC)		
	(NDSECNA)  96-N/A	
b. NDI contributing factors to cause of death, if applicable:(NDCONFAC)		
	(NDCNTNA)  96-N/A	
Comments:(NDICOMM)		
outside Control of the Control of th		

#### Overdose Events (ODE)

(xx) day(s)

beginein (FRO13EG).	
isit number (VISNO):	

- (xx) day(s)
- All questions relating to past 30 days refer to Days 1-30, post ED enrollment visit (Day 0).

  1. On how many days in the past 30 days do you think you overdosed on opioids (you used more opioids than you should have used and were more sedated, drugged, or high than you wanted to be)?(DDTHINK)

  2. On how many days in the past 30 days did you or someone else call for medical assistance because you were more sedated, drugged, or high than you should be after you used opioids?(ODMED)

  Comments:(ODECOMM)

Web Version: 1.0; 1.00; 03-08-17

## Other Substance Use (OSU)

Segment (PROTSEG): C Visit number (VISNO):

These questions ask about psychoactive substances in the PAST 3 MONTHS ONLY.		
1. Did you smoke a cigarette containing tobacco?(OSSMKCIG)	O-No	☐ 1-Yes
a. Did you usually smoke more than 10 cigarettes each day?(OSSMK10)	☐ 0-No	1-Yes
b. Did you usually smoke within 30 minutes after waking?(OSSMK30)	O-No	☐ 1-Yes
2. Did you have a drink containing alcohol?(OSALCOH)	O-No	☐ 1-Yes
a. On any occasion, did you drink more than 4 standard* drinks of alcohol? (*1 standard drink is about 1 small glass of wine, or one can of medium strength beer, or one single shot of spirits.)(OSALBING)	O-No	☐ 1-Yes
b. Have you tried and failed to control, cut down or stop drinking?(OSALSTOP)	☐ 0-No	1-Yes
c. Has anyone expressed concern about your drinking?(OSALCNR)	O-No	☐ 1-Yes
3. Did you use cannabis?(OSCANNAB)	O-No	☐ 1-Yes
a. Have you had a strong desire or urge to use cannabis at least once a week or more often?(OSCANDES)	☐ 0-No	1-Yes
b. Has anyone expressed concern about your use of cannabis?(OSCANCNR)	O-No	☐ 1-Yes
4. Did you use an amphetamine-type stimulant, or cocaine, or a stimulant medication not as prescribed?(OSSTMULN)	O-No	☐ 1-Yes
a. Did you use a stimulant at least once each week or more often?(OSSTMOFT)	☐ 0-No	1-Yes
b. Has anyone expressed concern about your use of a stimulant?(OSSTMCNR)	O-No	☐ 1-Yes
5. Did you use a sedative or sleeping medication not as prescribed?(OSSEDUSE)	O-No	☐ 1-Yes
<ul> <li>a. Have you had a strong desire or urge to use a sedative or sleeping medication at least once a week or more often? (OSSEDDES)</li> </ul>	O-No	☐ 1-Yes
b. Has anyone expressed concern about your use of a sedative or sleeping medication? (OSSEDSNR)	O-No	☐ 1-Yes
6. Did you use any other psychoactive altering substance?(OSPSYCH)	O-No	☐ 1-Yes
If "Yes", what did you take?(OSPSYSP)		
Comments:(OSUCOMM)		

/

Web Version: 1.0; 2.00; 06-25-18

## Protocol Deviation Review (PDR)

Date of deviation (PDDATE):
Protocol deviation number (PDSEQNO):

# Completed by Protocol Specialist:

What section of the protocol does this deviation refer to?(PDSECTN)	
Does the report of this deviation require site staff retraining?(PDTRAIN)  If "Yes", specify plan for retraining:(PDPLATRA)	O-No 1-Yes
Date deviation was discussed with Lead Investigative Team:(PDD/SCDT)	(mm/dd/yyyy)
Deviation is categorized as:(PDCATGRY)	2-Major 1-Minor
Deviation assessment by Protocol Specialist complete:(PDPSCMP)	☐ 0-No ☐ 1-Yes
Protocol Specialist reviewer:(PDPSRVID)	(initials)
Protocol Specialist comments:(PDRCOMM2)	
Troubon operation continuents. (F. B. Commu.)	
Completed by Protocol Monitor:	
Deviation requires review by Protocol Monitor:(PDPMREVW)	□ 0-No □ 1-Yes
Corrective action for this deviation was completed and documented on-site as described: (PDACTDOC)	□ 0-No □ 1-Yes
If "No", specify reason:(PDSITESP)	
Deviation was reported to the IRB as required:(PDIRBRPT)	☐ 0-No ☐ 1-Yes
If "No", specify reason:(PDIRBSP)	
Preventive action plan related to this event was completed and documented on-site as described: (PDPREVNT)	
Review by Protocol Monitor is complete:(PDPMCMP)	☐ 0-No ☐ 1-Yes ☐ 0-No ☐ 1-Yes
Protocol Monitor reviewer: (PDPMRVID)	U 0-No U 1-Yes (initials)
	(n nuclo)
Protocol Monitor comments:(PDRCOMM)	

1

Web Version: 1.0; 2.01; 08-20-18

## Additional Selection Options for PDR

Protocol deviation number (PDSEQNO) (key field):
01-1st Protocol Deviation of the day
02-2nd Protocol Deviation of the day
03-3rd Protocol Deviation of the day
03-3rd Protocol Deviation of the day
05-5th Protocol Deviation of the day
05-5th Protocol Deviation of the day
07-7th Protocol Deviation of the day
07-7th Protocol Deviation of the day
09-9th Protocol Deviation of the day
09-9th Protocol Deviation of the day

## Protocol Deviation (PDV)

Date of deviation (PDDATE):
Protocol deviation number (PDSEQNO):

Is this deviation related to one or more participants?(PDPPTREL)  If "Yes", how many participants?(PDPRELNO)				
Select related participants:				
Participant ID 1:(PDPPT01)				
Participant ID 2:(PDPPT02)  Participant ID 3:(PDPPT03)				
Participant ID 4:(PDPPT04)				
Participant ID 5:(PDPP105)				
Participant ID 6:(PDPPT06)				
Participant ID 7: (PDPPT07)				
Participant ID 8:(PDPPT08)				
Participant ID 9: (PDPPT09)				
Participant ID 10:(PDPPT10)				
Participant ID 11:(PDPPT11)				
Participant ID 12:(PDPPT12)				
Participant ID 13:(PDPPT13)				
Participant ID 14:(PDPPT14)				
Participant ID 15:(PDPPT15)				
Participant ID 16:(PDPPT16)				
Participant ID 17:(PDPPT17)				
Participant ID 18:(PDPPT18)				
Participant ID 19:(PDPPT19)				
Participant ID 20:(PDPPT20)				
2. Date deviation identified:(PDVDATE)				
3. Deviation type:(PDTYPE)				
If *Other*, specify:(PDTYPSP)				
Is this deviation related to COVID-19?(PDCVD19)     Brief description of what occurred:(PDDESCPT)				
6. Brief description of the actual or expected corrective action for this event: (PDACTION)				
7. Brief description of the plan to prevent recurrence:(PDPREVRE)				
8. Is this deviation reportable to your IRR2/PDIPRRFP)				

□ 0-No □ 1-Yes
01-1
02-2
03-3 04-4
05-5
*Additional Options Listed Below
¥
99999999999-DUMMYPARTICIPANTID
9999999999-DUMMYPARTICIPANTID A
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9999999999-DUMMYPARTICIPANTID A
9999999999-DUMMYPARTICIPANTID A
9999999999-DUMMYPARTICIPANTID
999999999-DUMMYPARTICIPANTID
(mm/dd/yyyy)
010-INFORMED CONSENT/ASSENT PROCEDURES 01A No consent/assent obtained 01B Invalid/incomplete informed consent/assent form 01C Unauthorized assessments and/or procedures conducted prior to obtaining informed consent/assent 01D Non IRB approved/outdated/obsolete informed consent/assent documents used *Additional Options Listed Below
□ 0-No □ 1-Yes
□ 0-No □ 1-Yes □ 0-No □ 1-Yes
(mm/dd/yyyy)

(mm/dd/yyyy)

If "Yes", will the IRB be notified at the time of continuing review? (PDIRBCON)

If "Yes", date of planned submission:(PDIRBPDT)

If "No", date of actual submission:(PDIRBADT)

Web Version: 1.0; 4.00; 09-11-20

#### **Additional Selection Options for PDV**

# Protocol deviation number (PDSEQNO) (key field): 01-1st Protocol Deviation of the day 02-2nd Protocol Deviation of the day 03-3rd Protocol Deviation of the day 03-3rd Protocol Deviation of the day 04-4th Protocol Deviation of the day 05-5th Protocol Deviation of the day 07-7th Protocol Deviation of the day 07-7th Protocol Deviation of the day 09-9th Protocol Deviation of the day 09-9th Protocol Deviation of the day If "Yes", how many participants? 06-6 07-7 08-8 09-9 10-10 11-11 12-12 13-13 14-14 15-15 16-16 17-17 18-18 19-19 19-19 20-20 Deviation type: 01E— Informed consent/assent process not properly conducted and/or documented 012— Other informed consent/assent procedures issues (specify) 020-INCLUSION/EXCLUSION CRITERIA 02A— Ineligible participant randomized/inclusion/exclusion criteria not met 02B— Ineligible participant randomized/inclusion/exclusion criteria not met 02B— Ineligible participant andomized/inclusion/exclusion criteria not met 02B— Ineligible participant andomized/inclusion/exclusion criteria not met 02B— Ineligible participant enrolled/inclusion/exclusion criteria insues (specify) 040-LABORATORY ASSESSMENTS 04A— Biologic specimen not collected/processed as per protocol 042— Other laboratory assessments issues (specify) 050-STUDY PROCEDURES/ASSESSMENTS 05A— Protocol required visitassessment not scheduled or conducted 05B— Study assessments not completed/followed as per protocol 05C— Inappropriate unbilinding 05Z— Other study procedures/assessments issues (specify) 060-ADVERSE EVENT 06A—AE not reported 06B—SaE not reported 06C— AE/SAE reported out of protocol specified reporting timeframe 06C— AE/SAE reported out of protocol specified reporting timeframe 06C— AE/SAE not elicited, observed and/or documented as per protocol 06Z— Other adverse events issues (specify) 07C-RANDOMIZATION PROCEDURES 07A—Stratification error 07CRANDOMIZATION PROCEDURES 07A—Stratification dispensed to ineligible participant 08B— Medication dispensed to ineligible participant 08 Over Study Behavioral intervention was not provided/performed as per protocol 099.-STUDY BEHAVIORAL INTERVENTION 099.-- Study behavioral intervention was not provided/performed as per protocol 092.-- Other study behavioral intervention issues (specify) 100-STUDY DEVICES 104.-- Study devices dispensed to ineligible participant 102.-- Other study devices issues (specify) 110-SAFETY EVENT 11A.-- Safety event not reported 11B.-- Safety event most reported out of protocol specified reporting timeframe 11C.-- Safety event not elicited, observed and/or documented as per protocol 11D.-- Safety event most elicited, observed and/or documented as per protocol 11D.-- Safety safety event issues (specify) 990-OTHER SIGNIFICANT DEVIATIONS 99A.-- Destruction of study materials without prior authorization from sponsor 99B.-- Berach of Confidentiality 99Z.-- Other significant deviations issues (specify)

CTN-0069 Annotated CRFs - Segment C		
NID	A Clinical Trials Network	
Stu	udy Completion (STC)	Web Version: 1.0; 8.00; 03-15-1
Segment (PROTSEG): C		
Did the participant complete the 30 day follow-up visit within 14 days of [insert enrollment date + 30d]?(STCOMPLT)     a. If "No," did the participant complete the 30 day follow-up visit at a later date?(STLTEFUP)     b. If "No", select the primary reason for not completing the follow-up visit:(STEARLY)	O-No 1-Yes O-No 1-Yes 1-Participant failed to return to clinic and unable to contact 2-Participant stopped participation due to practical problems (e.g., no childcare or transportation) 3-Participant moved from area 4-Participant incarcerated 5-Participant terminated due to AE/SAE *Additional Options Listed Below	
If "Participant terminated for other clinical reasons", "Participant terminated for administrative issues", or "Participant terminated for other reason", specify:(STCMPOSP)		
2. Date of last data collection or date of withdrawn consent:(STCOMPDT)	(mm/dd/yyyy)	
Comments:(STCCOMM)		
Investigator's Signature With this act of signing, I confirm that all data collected for this participant was under my guidance and the data submitted to	Advantage eClinical are complete and accurate to the best of my knowledge.	
Principal Investigator:(STPISIGN)		
Date:(STPISGDT)	(mm/dd/yyyy)	

#### **Additional Selection Options for STC**

- If "No", select the primary reason for not completing the follow-up visit:
- Participant failed to return to site and unable to contact
- Participant moved from area
- Participant incarcerated
- Participant terminated due to AE/SAE
- 8 Participant withdrew consent/assent
- 9 Participant deceased
- 12 Participant feels treatment no longer necessary, cured
- 13 Participant feels treatment no longer necessary, not working
- 14 Participant in hospital, in-patient, or residential treatment (not for substance use treatment)
- 20 Participant became pregnant
- 21 Participant reports intolerable symptoms or side effects
- 23 Clinical deterioration: New onset of psychiatric or medical condition
- 28 Participant is in detox, residential, or intensive outpatient treatment for substance use treatment
- 33 Participant met criteria for prisoner status
- 35 Contraindicated concomitant medication
- 36 Participant refused, non-specific
- 37 Physical illness or condition that precludes taking study medication
- 00 Participant terminated for other reaso

#### Timeline Followback Page 1 (T69)

TFB week start date (TFWKSTDT):

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	(TLDATE1)	(TLDATE2)	(TLDATE3)	(TLDATE4)	(TLDATE5)	(TLDATE6)	(TLDATE7)
Have any pain relievers, pain medications, sedatives, alcohol, methamphetamine, cocaine, heroin, or other illicit substances been used on this day?	(TLSUBAL1) 🗆 0-No 🗆 1-Yes	(TLSUBAL2) 0-No 1-Yes	(TLSUBAL3) 0-No 1-Yes	(TLSUBAL4) 🗆 0-No 🗆 1-Yes	(TLSUBAL5) 0-No 1-Yes	(TLSUBAL6) 0-No 1-Yes	(TLSUBAL7) 🗆 0-No 🗆 1-Yes
2. Heroin:							
Route:	(TLHERR1) 0-00-No use	(TLHERR2) 0-00-No use	(TLHERR3) 0-00-No use	(TLHERR4) 0-00-No use	(TLHERR5) 0-00-No use	(TLHERR6) 0-00-No use	(TLHERR7) 0-00-No use
	1-01-Oral						
	2-02-Nasal						
	3-03-Smoking 4-04-Non-IV Injection						
	*Additional Options Listed Below						
# Times Used Each Day:	(TLTHERR1) (XXX)	(TLTHERR2) (XXX)	(TLTHERR3) (xxx)	(TLTHERR4) (xxx)	(TLTHERR5) (xxx)	(TLTHERR6) (xxx)	(TLTHERR7) (xxx)
Oxycodone (Percocet, Percodan, Roxicet, Oxycotin, Roxicodone, Endocet, Tylox):							
Route:	(TLOXYC1) 0-00-No use	(TLOXYC2) 0-00-No use	(TLOXYC3) 0-00-No use	(TLOXYC4) 0-00-No use	(TLOXYC5) 0-00-No use	(TLOXYC6) 0-00-No use	(TLOXYC7) 0-00-No use
	1-01-Oral						
	2-02-Nasal						
	3-03-Smoking 4-04-Non-IV Injection						
	*Additional Options Listed Below						
Prescribed:	(TLPOXYC1) 0-No 1-Yes	(TLPOXYC2) 0-No 1-Yes	(TLPOXYC3) 0-No 1-Yes	(TLPOXYC4) 0-No 1-Yes	(TLPOXYC5) 0-No 1-Yes	(TLPOXYC6) 0-No 1-Yes	(TLPOXYC7) 0-No 1-Yes
# Times Used Each Day:	(TLTOXYC1) (XXX)	(TLTOXYC2) (xxx)	(TLTOXYC3) (xxx)	(TLTOXYC4) (XXX)	(TLTOXYC5) (XXX)	(TLTOXYC6) (xxx)	(TLTOXYC7) (xxx)
4. Hydrocodone (Vicodin, Lorcet, Lortab, Hycodan, Norco, Vicoprofen):							
Route:	(TLHYDC1)	(TLHYDC2)	(TLHYDC3)	(TLHYDC4)	(TLHYDC5)	(TLHYDC6)	(TLHYDC7)
	0-00-No use 1-01-Oral						
	2-02-Nasal						
	3-03-Smoking						
	4-04-Non-IV Injection *Additional Options Listed Below	*Additional Options Listed Below	4-04-Non-IV Injection *Additional Options Listed Below	4-04-Non-IV Injection *Additional Options Listed Below	4-04-Non-IV Injection *Additional Options Listed Below	4-04-Non-IV Injection *Additional Options Listed Below	4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPHYDC1) 0-No 1-Yes	(TLPHYDC2) 0-No 1-Yes	(TLPHYDC3) 0-No 1-Yes	(TLPHYDC4) 0-No 1-Yes	(TLPHYDC5) 0-No 1-Yes	(TLPHYDC6) 0-No 1-Yes	(TLPHYDC7) 0-No 1-Yes
# Times Used Each Day:	(TLTHYDC1) (XXX)	(TLTHYDC2) (XXX)	(TLTHYDC3) (xxx)	(TLTHYDC4) (XXX)	(TLTHYDC5) (xxx)	(TLTHYDC6) (xxx)	(TLTHYDC7) (xxx)
Fentanyl (Duragesic, Actiq, Sublimaze):							
Route:	(TLFENT1)	(TLFENT2)	(TLFENT3)	(TLFENT4)	(TLFENT5)	(TLFENT6)	(TLFENT7)
	0-00-No use 1-01-Oral	0-00-No use	0-00-No use 1-01-Oral	0-00-No use	0-00-No use 1-01-Oral	0-00-No use 1-01-Oral	0-00-No use
	2-02-Nasal						
	3-03-Smoking						
	4-04-Non-IV Injection *Additional Options Listed Below						
	Additional Options Listed Below						
Prescribed:	(TLPFENT1) 0-No 1-Yes	(TLPFENT2) 0-No 1-Yes	(TLPFENT3) 0-No 1-Yes	(TLPFENT4) 0-No 1-Yes	(TLPFENT5) 0-No 1-Yes	(TLPFENT6) 0-No 1-Yes	(TLPFENT7) 🗆 0-No 🗆 1-Yes
# Times Used Each Day:	(TLTFENT1) (xxx)	(TLTFENT2) (xxx)	(TLTFENT3) (xxxx)	(TLTFENT4) (xxx)	(TLTFENT5) (xxx)	(TLTFENT6) (xxx)	(TLTFENT7) (xxx)
6. Morphine (MS Contin, Kadian, Duramorph):							
Route:	(TLMORH1) 0-00-No use	(TLMORH2)	(TLMORH3) 0-00-No use	(TLMORH4)	(TLMORH5) 0-00-No use	(TLMORH6) 0-00-No use	(TLMORH7) 0-00-No use
	1-01-Oral	0-00-No use 1-01-Oral	1-01-Oral	0-00-No use 1-01-Oral	1-01-Oral	0-00-No use 1-01-Oral	0-00-No use
	2-02-Nasal						
	3-03-Smoking 4-04-Non-IV Injection						
	*Additional Options Listed Below						
Prescribed:	(TLPMORH1)	(TLPMORH2) 0-No 1-Yes	(TLPMORH3) 0-No 1-Yes	(TLPMORH4) 0-No 1-Yes	(TLPMORH5) 0-No 1-Yes	(TLPMORH6) 0-No 1-Yes	(TLPMORH7) 0-No 1-Yes
#Times Used Each Day:	(TLTMORH1) (xxx)	(TLTMORH2) (xxx)	(TLTMORH3) (xxx)	(TLTMORH4) (xxx)	(TLTMORH5) (xxx)	(TLTMORH6) (xxx)	(TLTMORH7) (xxx)
7. Hydromorphone (Dilaudid, Palladone):						Ï	
Route:	(TLHYMR1)	(TLHYMR2)	(TLHYMR3)	(TLHYMR4)	(TLHYMR5)	(TLHYMR6)	(TLHYMR7)
							,
		II	II			II	Dama 40

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CTN-0069 Annotated CRFs - Segment C 0-00-No use 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 4-04-Non-IV Injection \*Additional Options Listed Below Prescribed: (TLPHYMR1) 0-No 1-Yes (TLPHYMR2) 0-No 1-Yes (TLPHYMR3) 0-No 1-Yes (TLPHYMR4) 0-No 1-Yes (TLPHYMR5) 🗌 0-No 🔲 1-Yes (TLPHYMR6) 0-No 1-Yes (TLPHYMR7) 0-No 1-Yes # Times Used Each Day (TI THYMR1) (XXX) (TLTHYMR2) (xxx) (TITHYMR3) (xxx) (TI THYMR4) (yyy) (TI THYMR5) (xxx) (TLTHYMR6) (yyy) (TLTHYMR7) (xxx) 8. Meperidine (Demerol): Route (TLMEPR1) (TLMEPR2) TI MEPR3 (TLMEPR4) (TLMEPR5) (TLMEPR6) (TLMEPR7) 0-00-No use 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 4-04-Non-IV Injection \*Additional Options Listed Below Prescribed: (TLPMEPR1) 0-No 1-Yes (TLPMEPR2) 0-No 1-Yes (TLPMEPR3) 0-No 1-Yes (TLPMEPR4) 0-No 1-Yes (TLPMEPR5) 0-No 1-Yes (TLPMEPR6) 0-No 1-Yes (TLPMEPR7) 0-No 1-Yes # Times Taken Each Day: (TLTMEPR1) (TLTMEPR7) (xxx) (TLTMEPR2) (XXX) (TLTMEPR3) (xxx) (TLTMFPR4) (xxx) (TLTMEPR5) (TLTMEPR6) (XXX) (xxx) 9. Methadone (Dolophine, Methadose) (TLMEDN1) (TLMEDN2) TLMEDN3) TLMEDN4) (TLMEDN5) TLMEDN6) (TLMEDN7) 0-00-No use 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 4-04-Non-IV Injection \*Additional Options Listed Below Prescribed: (TLPMEDN1) 0-No 1-Yes (TLPMEDN2) 0-No 1-Yes (TLPMEDN4) 0-No 1-Yes (TLPMEDN6) 0-No 1-Yes (TLPMEDN3) 0-No 1-Yes (TLPMEDN5) 0-No ☐ 1-Yes (TLPMEDN7) 0-No 1-Yes # Times Used Each Day (TLTMEDN1) (TLTMEDN2) (TLTMEDN3) (TLTMEDN4) (TLTMEDN5) (TLTMEDN6) (TLTMEDN7) 10. Buprenorphine (Suboxone, Zubsolv, Bunavail): (TLBUPR1) (TLBUPR2) TLBUPR3) (TLBUPR4) (TLBUPR5) (TLBUPR6) (TLBUPR7) 0-00-No use 0-00-No use 1-00-No use 0-00-No use 0-00-No use 0-00-No use 0-00-No use 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 4-04-Non-IV Injection \*Additional Options Listed Below \*Additional Options Listed Below Additional Options Listed Below \*Additional Options Listed Below \*Additional Options Listed Below \*Additional Options Listed Below \*Additional Options Listed Below Prescribed: (TLPBUPR1) 0-No 1-Yes (TLPBUPR2) 0-No 1-Yes (TLPBUPR3) 0-No 1-Yes (TLPBUPR4) 0-No 1-Yes (TLPBUPR5) 0-No 1-Yes (TLPBUPR6) 0-No 1-Yes (TLPBUPR7) 0-No 1-Yes # Times Used Each Day: (TLTBUPR1) (TLTBUPR2) (TLTBUPR3) (xxx) (TLTBUPR4) (TLTBUPR5) (TLTBUPR6) (TLTBUPR7) (xxx) 11. Oxymorphone (Opana): (TLOXYM1) (TLOXYM2) (TLOXYM3) (TLOXYM4) (TLOXYM5) (TLOXYM6) (TLOXYM7) 0-00-No use 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 1-01-Oral 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 2-02-Nasal 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 3-03-Smoking 4-04-Non-IV Injection \*Additional Options Listed Below Prescribed: (TLPOXYM1) 0-No 1-Yes (TLPOXYM2) 0-No 1-Yes (TLPOXYM3) 0-No 1-Yes (TLPOXYM4) 0-No 1-Yes (TLPOXYM5) 0-No 1-Yes (TLPOXYM6) 0-No 1-Yes (TLPOXYM7) 0-No 1-Yes # Times Used Each Day: (TLTOXYM1) (TLTOXYM2) (TLTOXYM3) (TLTOXYM4) (TLTOXYM5) (TLTOXYM6) (TLTOXYM7) (xxx) Comments:(TFBCOMM)

## **Additional Selection Options for T69**

**D1 heroin** 5-05-IV Injection 99-99-Other

Segment (PROTSEG): C Visit number (VISNO):

#### **NIDA Clinical Trials Network**

#### TLFB Assessment Period (TAP)

Target day for 30 day followup: (TAPASMDT)

1. Assessment period: (TATFSTDT)

1. Assessment period: (TATFSTDT)

1. To: (mm/dd/yyyy)

1. The following substances were indicated by the participant as used during the past 30 days on the ED Health Quiz: [insert reported names of substances indicated on Q7 and Q9 on EHQ]

1. The following days were indicated by the participant as days any prescription opioids, pain relievers or heroin were used during the past 7 days on the ED Health Quiz: [insert reported days of use from EHQ]

2. Have any substances, alcohol, cigarettes, or e-cigarettes been used during this assessment period? (TASUBALC)

2. Does the participant have a prescription for any substances including opiates and marijuana for any days in this assessment

3. Does the participant have a prescription for any substances including opiates and marijuana for any days in this assessment

3. Does the participant have a prescription for any substances including opiates and marijuana for any days in this assessment

3. Does the participant have a prescription for any substances including opiates and marijuana for any days in this assessment

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3. Does the participant have a prescription for any substances including opiates and marijuana for any days in this assessment

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# Urine Drug Screen (UDS)

Segment (PROTSEG): C	
Visit number (VISNO):	

1. Was a urine drug screen performed?(UDTEST1)

If "No", reason:(UDNORSN1)

If "Other", specify:(UDNOSP1)

2. Date urine specimen collected:(UDCOLDT)

3. Urine Drug Screen Result(s):

Comments:(UDSCOMM)

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO1)		
Amphetamine (AMP):	(UDAMP1)		
Marijuana (THC):	(UDTHC1)		
Methamphetamine (MET):	(UDMET1)		
Opiates (2000 ng) (OPI):	(UDOPI1)		
Cocaine (COC):	(UDCOC1)		
Ecstasy (MDMA):	(UDMDA1)		
Oxycodone (OXY):	(UDOXY1)		
Methadone (MTD):	(UDMTD1)		
Barbiturate (BAR):	(UDBAR1)		
Opiates (300 ng) (OPI):	(UDOPI31)		
Buprenorphine (10 ng) (BUP):	(UDBUP1)		
Fentanyl (FEN):	(UDFEN1)		

□ 0-No □ 1-Yes 1-Participant reported being unable to provide sample ▲		
-Participan	refused to provide sample	
-Study staf	error	
9-Other		
	(mm/dd/yyyy)	

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