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Version: 1.05; 01-20-23

### Eligibility Review (EL2)

Segment (PROTSEG): A

Visit Number (VISNO):	
Date of assessment:(ELRASMDT)	(mm/dd/yyyy)
Screening Inclusion Criteria  1. Which clinic do you go to?(ELCLINIC)	
	01-Clinic 1 02-Clinic 2
2. Which clinic do you go to?(ELCLINIC)	□ 01-Clinic 1 □ 02-Clinic 2 □ 03-Clinic 3
3. Which clinic do you go to?(ELCLINIC)  4. Who is your primary care provider?	
	wn list, based on the name the patient participant just gave. Remember you can double check you  PXXXXXXX-PROVIDERID
(FL DODALOD)	Provider ID: PXXXXXXX1-PROVIDERID1
(ELPCPNOP)	01- Provider not participating
5. Do you have access to a phone that can receive text messages and phone calls? [Must be "Yes"](ELPHNTXT)	□ 0-No □ 1-Yes
6. Do you have access to the internet at least once per week, via a phone, tablet, and/or computer? [Must be "Yes"](ELINTNT) Acceptable (Internet at least once per week, via a phone, tablet, and/or computer? [Must be "Yes"](ELINTNT)	□ 0-No □ 1-Yes
7. Are you currently following a diet plan to lose weight?(ELDIETPL)	□ 0-No □ 1-Yes
<ol> <li>Do you currently pay for any fitness services such as a gym membership, classes, etc.?(ELGYMFIT)</li> </ol>	, □ 0-No □ 1-Yes
9. Have you been receiving medication for opioid use disorder such as buprenorphine (Suboxone) or Vivitrol (which is a once per month injection), or have you been engaged in a methadone treatment program in the past 30 days? [Must be "No"](ELOUDMED)	□ 0-No □ 1-Yes
10. Are you currently receiving opioid pain medications for end of life care? [Must be "No"]	□ 0-No □ 1-Yes
Opioid pain medications include medications like morphine (MS-Contin), oxycodone (OxyContin, Percocet), hydrocodone (Vicodin), methadone, codeine, tramadol (Ultram) and similar pain medications that require a prescription from a medical provider.(ELOPIEOL)	
11. Do you have <u>definite and irreversible</u> plans to leave the area or stop receiving care at this primary care clinic within the next 12 months? [Must be "No"]	e ☐ 0-No ☐ 1-Yes
Definite and irreversible means you have already accepted a job in another area o have a plane ticket to your next location.(ELLEAVE)	or
12. If you decide to enroll in the study, would you be willing to provide contact information for one or more of your family members, friends, or any individuals who could help us reach you in case we have trouble getting in touch? [Must be "Yes"](ELCNTACT)	□ 0-No □ 1-Yes
13. Are you pregnant? [Must be "No" or "N/A"](ELPREGNT)	□ 00-No □ 01-Yes □ 96-N/A
14. Is the patient participant still eligible for the study?(ELSTLELG)	□ 0-No □ 1-Yes
methadone and buprenorphine (Suboxone). Opioid pain medications include medi Norco), methadone, codeine, tramadol (Ultram) and similar pain medications that in These questions refer to the past 12 months, meaning starting from today and goin	ions, illegal opioid drugs like heroin and fentanyl, and medications used for addiction treatment like ications like morphine (MS-Contin), oxycodone (OxyContin, Percocet), hydrocodone (Vicodin, require a prescription from a medical provider.  In back to one year ago. Please answer 'yes' or 'no' to each question. If you do not understand the ninutes to complete. Please remember that all of your responses are confidential, and will not be
15. Was there ever a time in the last 12 months when your use of OPIOIDS frequently interfered with your work or responsibilities at school, on a job, or at home? (KEY PHRASE: interfered with your work or school)(ELINTERF)	′ □ 0-No □ 1-Yes

16. Was there ever a time in the last 12 months when your use of OF arguments or other serious or repeated problems with your family neighbors, or co-workers?( <i>ELARGMNT</i> )		□ 0-No	1-Yes	
17. Did you continue to use OPIOIDS even though it caused problem people? (KEY PHRASE: caused problems with family or friends)(ELPEOF		□ 0-No	1-Yes	
18. Were there times in the last 12 months when you were often undo OPIOIDS in situations where you could have gotten hurt - for exa a bicycle, driving, operating a machine, or anything else?  (KEY PHRASE: occurred in situations where you could have gott (ELHURT)	mple when riding	□ 0-No	1-Yes	
19. In the last 12 months, were you arrested or stopped by the police because of driving under the influence of OPIOIDS or because of while you were under the influence of OPIOIDS?  (KEY PHRASE: resulted in problems with the police)(ELPOLICE)	f your behavior	□ 0-No	☐ 1-Yes	
20. Was there ever a time in the last 12 months when you often had desire to use OPIOIDS that you couldn't stop using or found it differ anything else? (KEY PHRASE: you had a strong and irresistible urge to use OPI (ELDIFSTP)	ficult to think of	□ 0-No	1-Yes	
21. In the last 12 months, did you ever need larger amounts of OPIO effect, or did you ever find that you could no longer get high on the used to use?  (KEY PHRASE: you needed larger amounts of OPIOIDS to get a (ELNEEDMR)	e amount you	O-No	1-Yes	
22. Was there ever a time in the last 12 months when you stopped, c without using OPIOIDS and then experienced withdrawal symptom (KEY PHRASE: you experienced withdrawal symptoms from OPI (ELEXPWDL)	ms?	□ 0-No	☐ 1-Yes	
23. Did you ever have times in the last 12 months when you used OF from having withdrawal symptoms? (KEY PHRASE: you used OPIOIDS to keep from feeling physical (ELSTPWDL)	•	□ 0-No	1-Yes	
24. Did you ever have times in the last 12 months when you used OF though you planned not to or when you used a lot more than you (KEY PHRASE: you used when you planned not to or you used in planned)(ELUSEMR)	intended?	□ 0-No	1-Yes	
25. Were there times in the last 12 months when you used OPIOIDS or for more days in a row than you intended? (KEY PHRASE: you used more frequently than you intended)(EL		□ 0-No	1-Yes	
26. Were there times in the last 12 months when you tried to stop or use of OPIOIDS and found that you were not able to do so? (KEY PHRASE: you tried but weren't able to stop or cut down using the stop of the s		□ 0-No	1-Yes	
27. In the last 12 months, did you ever have several days or more who much time using or getting over the effects of OPIOID use that you for anything else? (KEY PHRASE: you spent periods of several days doing little mongetting over the effects of using)(ELNOTIME)	ou had little time	□ 0-No	1-Yes	
28. In the last 12 months, was there ever a time when you gave up o important activities because of your OPIOID use - for example, speeing friends and family?  (KEY PHRASE: you gave up or greatly reduced important activiting your use) (ELGAVEUP)	ports, work, or	□ 0-No	1-Yes	
29. In the last 12 months, did you ever continue to use OPIOIDS who had a serious physical or emotional problem that might have bee made worse by using OPIOIDS?  (KEY PHRASE: you continued to use even though it caused or wor emotional problems)(ELOPIPRB)	n caused by or	O-No	1-Yes	
(ELCIDISC)		CIDI Scor	re:	(xx)

### **Prisoner Status Assessment**

The next set of questions will ask you about any current involvement with the crimi Protections considers a prisoner. Your information will be kept confidential and will	inal justice system, as our study is not able to enroll persons who the Office for Human Researc not be shared with your provider. These questions are asked of all participants.
30. Are you currently being made to stay in an institution (such as a substance use treatment program), by sentence of a court, due to a criminal or civil proceeding? (ELINST)	□ 0-No □ 1-Yes
31. Are you currently being detained while awaiting trial, arraignment, or sentencing? (ELTRIAL)	□ 0-No □ 1-Yes
<ol> <li>Are you currently being detained as an alternative to criminal prosecution or incarceration in a jail or prison?(ELDETALT)</li> </ol>	□ 0-No □ 1-Yes
33. Are you currently under house arrest, such that you are escorted to treatment or, upon discharge from treatment, you will be escorted to jail, prison, or any inpatient overnight facility as required by law?(ELPROBHA)	□ 0-No □ 1-Yes
For the Research Coordinator do not ask the pati	ent participant:
34. Does the participant meet the definition of "prisoner" by any local or state regulations? (ELPRISON)	□ 0-No □ 1-Yes
35. Are there any other factors that may cause harm or increase risk to the patient participant or close contacts or preclude the patient participant's full adherence with or completion of the study? [Must be "No"](ELHARM)	□ 0-No □ 1-Yes
36. Is the patient participant able to understand the basic study procedures described in English, in the written consent form? [Must be "Yes"](ELENGLSH)	□ 0-No □ 1-Yes
37. Is the patient participant able to provide informed consent? [Must be "Yes"] (ELCNSNT)	□ 0-No □ 1-Yes
38. Is patient participant eligible for enrollment into the study?(ELSTELIG)	□ 0-No □ 1-Yes
39. If patient participant is eligible, will they be enrolled into the study?(ELSTENRO)	
a. If "No", specify:(ELNOENRN)	04-Unable to contact 05-Time commitment 00-No longer interested in participating in the study 02-Judgment of site/research staff 92-COVID-19: Illness *Additional Options Listed Below
1. If "Other", specify:(ELNOERSP)	
40. What type of consent was obtained for the patient participant prior to the PCP visit?(ELCNSTTY)	01-Verbal 02-Written/Electronic
a. Date of consent:(ELCNSTDT)	(mm/dd/yyyy)
Please assign the following script materials during the patient participant's PCP visit:(ELSCRIPT)	
Comments:(ELRCOMM)	

# Additional Selection Options for EL2

If "No", specify: 93-COVID-19: Public health measures 94-COVID-19: Other 99-Other



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Version: 1.00; 02-21-24

### 0101A (ENR)

- 1. Date participant agreed to continue eligibility screening:(STARTDT)
- 2. Unique survey ID:(S01UQID)
- 3. Which PCP brief advice script/video doctor could the participant be assigned to according to the Healthy Living Eligibility Report?(S01ADVIC)
  Comments:(S01COMM)

	(mm/dd/yyyy)	
01-Illicit	02-Prescribed	



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Version: 2.00; 06-18-21

## **Provider Eligibility Review (PCP)**

Provider study ID (PCPID):

Date PCP eligibility assessed: (PCELGDT)  (.What is the name of the provider? (PCPCPNAM)  2. Is the PCP currently providing care to approximately 4 or more adult patients (18 years or older) who are receiving chronic opioid treatment and/or have risky opioid use?  Chronic opioid treatment is defined as having at least three opioid prescriptions, at least 21 days part, in the past six months, with EHR documentation of active opioid prescription within the 60 days prior to screening. For PCPs who practice in a team, the care of patients receiving chronic opioid treatment may be shared with other team members who also meet criteria for participation in the study. (PCOPI)  3. is the PCP's total patient volume approximately 40 or more adult patients (18 years or older) per week on a typical week (excluding vacation and inpatient rounding weeks)?  (PCPVOL)  Screening Survey [Pyperlink1]  Eligibility for Randomization into Study  4. Is the provider eligible for randomization into the study? (PCELIG)  5. If provider is eligible, have they provided signed informed consent and will they be randomized into the study? (PCICFRAN)  a. If "No", specify: (PCNORAND)  O4-Unable to contact  05-Time commitment  00-No longer interested in participating in the study 02-Judgment of site/research staff 92-COVID-19: Illness  *Additional Options Listed Below  1. If "Other", specify: (PCNORNSP)  b. If "Yes", date of informed consent: (PCICFDT)  Post Randomization Surveys  Baseline Assessment Survey [Pyperlink2]  End of Intervention Survey  Check this box if it's time to send the End of Intervention Survey: (PCENDINT)  [Pyperlink3]  Post-Randomization Dropout  5. Indicate the reason the provider withdrew early from the study: (PCWITDRW)  10-Plans to leave the practice  11-Reduced patient panel	Eligibility Review	
2. Is the PCP currently providing care to approximately 4 or more adult patients (18 years or older) who are receiving chronic opioid treatment and/or have risky opioid use?  Chronic opioid treatment is defined as having at least three opioid prescriptions, at least 21 days apart, in the past six months, with EHR documentation of active opioid prescription within the 60 days prior to screening. For PCPs who practice in a team, the care of patients receiving chronic opioid treatment may be shared with other team members who also meet criteria for participation in the study (PCOPI)  3. Is the PCP's total patient volume approximately 40 or more adult patients (18 years or older) per week on a typical week (excluding vacation and inpatient rounding weeks)?  (PCPVOL)  Screening Survey [hyperlink1]  Eligibility for Randomization into Study  4. Is the provider eligible for randomization into the study?(PCELIG)  5. If "No", specify:(PCNORAND)  1. If "Other", specify:(PCNORAND)  1. If "Other", specify:(PCNORNSP)  5. If "Yes", date of informed consent:(PCICFDT)  Post Randomization Survey [hyperlink2]  Post-Randomization Dropout  5. Indicate the reason the provider withdrew early from the study:(PCWTDRW)  10Plans to leave the practice	Date PCP eligibility assessed:(PCELGDT)	(mm/dd/yyyy)
years or older) who are receiving chronic opioid treatment and/or have risky opioid use?  Chronic opioid treatment is defined as having at least three opioid prescriptions, at least 21 days part, in the past six months, with EHR documentation of active opioid prescription within the 60 days prior to screening. For PCPs who practice in a team, the care of patients receiving chronic opioid treatment may be shared with other team members who also meet criteria for participation in the study (PCOPI)  S. is the PCP's total patient volume approximately 40 or more adult patients (18 years or older) per week on a typical week (excluding vacation and inpatient rounding weeks)?  (PCPVOL)  Screening Survey [hyperlink1]  Eligibility for Randomization into Study  1. If "No", specify:(PCNORAND)  A. If "No", specify:(PCNORAND)  T. If "Other", specify:(PCNORNSP)  b. If "ves", date of informed consent:(PCICFDT)  Post Randomization Survey [hyperlink2]  End of Intervention Survey Check this box if it's time to send the End of Intervention Survey:(PCENDINT) [hyperlink3]  Post-Randomization Dropout  5. Indicate the reason the provider withdrew early from the study:(PCWTDRW)	I. What is the name of the provider?(PCPCPNAM)	
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Screening Survey [/hyperlink1]  Eligibility for Randomization into Study 4. Is the provider eligible for randomization into the study?(PCELIG) 5. If provider is eligible, have they provided signed informed consent and will they be randomized into the study?(PCICFRAN) a. If "No", specify:(PCNORAND)  0No	Chronic opioid treatment is defined as having at least three opioid prescriptions, at least 21 days apart, in the past six months, with EHR documentation of active opioid prescription within the 60 days prior to screening. For PCPs who practice in a team, the care of patients receiving chronic opioid treatment may be shared with other team members who also meet criteria for participation in the study.(PCOPI) 3. Is the PCP's total patient volume approximately 40 or more adult patients (18 years or older) per week on a typical week (excluding vacation and inpatient	□ 0-No □ 1-Yes
Eligibility for Randomization into Study  4. Is the provider eligible for randomization into the study?(PCELIG)  5. If provider is eligible, have they provided signed informed consent and will they be randomized into the study?(PCICFRAN)  a. If "No", specify:(PCNORAND)  04-Unable to contact 05-Time commitment 00-No longer interested in participating in the study 02-Judgment of site/research staff 92-COVID-19: Illness "Additional Options Listed Below  1. If "Other", specify:(PCNORNSP)  b. If "Yes", date of informed consent:(PCICFDT)  Post Randomization Surveys Baseline Assessment Survey [hyperlink2]  End of Intervention Survey Check this box if it's time to send the End of Intervention Survey:(PCENDINT) [hyperlink3]  Post-Randomization Dropout 6. Indicate the reason the provider withdrew early from the study:(PCWITDRW)  10-Plans to leave the practice	Screening Survey	
4. Is the provider eligible for randomization into the study?(PCELIG)  5. If provider is eligible, have they provided signed informed consent and will they be randomized into the study?(PCICFRAN)  a. If "No", specify:(PCNORAND)  04-Unable to contact 05-Time commitment 00-No longer interested in participating in the study 02-Judgment of site/research staff 92-COVID-19: Illness "Additional Options Listed Below  1. If "Other", specify:(PCNORNSP)  b. If "Yes", date of informed consent:(PCICFDT)  Post Randomization Surveys Baseline Assessment Survey [hyperlink2]  End of Intervention Survey Check this box if it's time to send the End of Intervention Survey:(PCENDINT) [hyperlink3]  Post-Randomization Dropout 6. Indicate the reason the provider withdrew early from the study:(PCWITDRW)  10-Plans to leave the practice	• • •	
5. If provider is eligible, have they provided signed informed consent and will they be randomized into the study?(PCICFRAN) a. If "No", specify:(PCNORAND)  4. Unable to contact 05-Time commitment 00-No longer interested in participating in the study 02-Judgment of site/research staff 92-COVID-19: Illness "Additional Options Listed Below  1. If "Other", specify:(PCNORNSP) b. If "Yes", date of informed consent:(PCICFDT)  Post Randomization Surveys Baseline Assessment Survey [hyperlink2]  End of Intervention Survey Check this box if it's time to send the End of Intervention Survey:(PCENDINT)		
randomized into the study?(PCICFRAN) a. If "No", specify:(PCNORAND)  Q4-Unable to contact 05-Time commitment 00-No longer interested in participating in the study 02-Judgment of site/research staff 92-COVID-19: Illness *Additional Options Listed Below  1. If "Other", specify:(PCNORNSP) b. If "Yes", date of informed consent:(PCICFDT)  Post Randomization Surveys Baseline Assessment Survey [hyperlink2]  End of Intervention Survey Check this box if it's time to send the End of Intervention Survey:(PCENDINT) [hyperlink3]  Post-Randomization Dropout 6. Indicate the reason the provider withdrew early from the study:(PCWITDRW)  10-Plans to leave the practice	, , ,	
05-Time commitment 00-No longer interested in participating in the study 02-Judgment of site/research staff 92-COVID-19: Illness *Additional Options Listed Below  1. If "Other", specify:(PCNORNSP)  b. If "Yes", date of informed consent:(PCICFDT)  Post Randomization Surveys Baseline Assessment Survey [hyperlink2]  End of Intervention Survey Check this box if it's time to send the End of Intervention Survey:(PCENDINT) [hyperlink3]  Post-Randomization Dropout 6. Indicate the reason the provider withdrew early from the study:(PCWITDRW)  10-Plans to leave the practice		U 0-No U 1-Yes
00-No longer interested in participating in the study 02-Judgment of site/research staff 92-COVID-19: Illness *Additional Options Listed Below  1. If "Other", specify:(PCNORNSP)  b. If "Yes", date of informed consent:(PCICFDT)  Post Randomization Surveys Baseline Assessment Survey [hyperlink2]  End of Intervention Survey Check this box if it's time to send the End of Intervention Survey:(PCENDINT)  [hyperlink3]  Post-Randomization Dropout 6. Indicate the reason the provider withdrew early from the study:(PCWITDRW)  10-Plans to leave the practice	a. If "No", specify:(PCNORAND)	
b. If "Yes", date of informed consent:(PCICFDT)  Post Randomization Surveys Baseline Assessment Survey [hyperlink2]  End of Intervention Survey Check this box if it's time to send the End of Intervention Survey:(PCENDINT) [hyperlink3]  Post-Randomization Dropout 6. Indicate the reason the provider withdrew early from the study:(PCWITDRW)  10-Plans to leave the practice		00-No longer interested in participating in the study 02-Judgment of site/research staff 92-COVID-19: Illness
b. If "Yes", date of informed consent: (PCICFDT)  Post Randomization Surveys Baseline Assessment Survey [hyperlink2]  End of Intervention Survey Check this box if it's time to send the End of Intervention Survey: (PCENDINT) [hyperlink3]  Post-Randomization Dropout 6. Indicate the reason the provider withdrew early from the study: (PCWITDRW)  [10-Plans to leave the practice	1 If "Other" specify:(PCNORNSP)	
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Check this box if it's time to send the End of Intervention Survey: (PCENDINT)  [hyperlink3]  Post-Randomization Dropout  6. Indicate the reason the provider withdrew early from the study: (PCWITDRW)  10-Plans to leave the practice	Post Randomization Surveys Baseline Assessment Survey	(min/ad/yyyy)
6. Indicate the reason the provider withdrew early from the study:(PCWITDRW) 10-Plans to leave the practice	Check this box if it's time to send the End of Intervention Survey: (PCENDINT)	□ 01-
6. Indicate the reason the provider withdrew early from the study:(PCWITDRW) 10-Plans to leave the practice	Post-Randomization Dropout	
00-No longer interested in participating in the study 02-Judgement of site/research staff 99-Other	-	11-Reduced patient panel 00-No longer interested in participating in the study 02-Judgement of site/research staff
a. If "Other", specify:(PCWTDRSP)	a. If "Other", specify:(PCWTDRSP)	
b. Date of early withdrawal:(PCWTDRDT) (mm/dd/yyyy)	b. Date of early withdrawal:(PCWTDRDT)	(mm/dd/yyyy)
Comments:(PCPCOMM)	Comments:(PCPCOMM)	//

## Additional Selection Options for PCP

Provider study ID (PCPID) (key field):

PXXXXXXXX-PROVIDERID PXXXXXXX1-PROVIDERID1

If "No", specify:

93-COVID-19: Public health measures

94-COVID-19: Other

99-Other



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#### Version: 5.01; 03-15-24

### **Protocol Deviation (PDV)**

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

Is this deviation related to one or more participants?(PDPPTREL)
 a. 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:(PDPPT05) 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)

9999999999999-DUMMYPARTICIPANTID 9999999999999-DUMMYPARTICIPANTID 9999999999999-DUMMYPARTICIPANTID 99999999999999-DUMMYPARTICIPANTID 99999999999999-DUMMYPARTICIPANTID 9999999999999-DUMMYPARTICIPANTID 99999999999999-DUMMYPARTICIPANTID 9999999999999-DUMMYPARTICIPANTID 9999999999999-DUMMYPARTICIPANTID 99999999999999-DUMMYPARTICIPANTID 9999999999999-DUMMYPARTICIPANTID 9999999999999-DUMMYPARTICIPANTID 9999999999999-DUMMYPARTICIPANTID

2. Date deviation identified: (PDVDATE)

(mm/dd/yyyy)

3. Deviation type:(PDTYPE)	01A N 01B U 01C N 01Y O	ORMED CONSENT/ASSENT PROCEDURES to consent/assent obtained inauthorized assessments and/or procedures conducted prior to obtaining informed consent/assent lon IRB approved/outdated/obsolete informed consent/assent documents used ther major informed consent/assent procedures issues (specify) all Options Listed Below	•
a. If "Other", specify:(PDTYPSP)			
4. Reason for Protocol Deviation: (select all that apply) a. Research staff error:(PDRSSTFF)		<i>Z</i>	
b. Hospital error:(PDRSHSP)		☐ 1-Yes	
c. Facility (e.g., hospital, clinic) error:(PDRSHSP)		□ 1-Yes □ 1-Yes	
d. Laboratory error:(PDRSLAB)		<u> </u>	
e. Pharmacy error:(PDRSPHRM)		☐ 1-Yes ☐ 1-Yes	
f. Equipment/supply failure:(PDRSEQSP)	_		
g. Issue with Advantage eClinical (e.g., system down, system glitch):(PDRSEDC)		☐ 1-Yes ☐ 1-Yes	
h. Participant unable to comply:(PDRSPTNC)	□ 0-No	1-Yes	
i. Participant refusal:(PDRSPTRF)		1-Yes	
j. Investigator/study decision:(PDRSINDC)		1-Yes	
k. Other:(PDRSOTHR)		1-Yes	
1. If "Other", specify:(PDRSOTSP)			
5. Is this deviation related to COVID-19?(PDCVD19)	0-No		
6. Brief description of what occurred:(PDDESCPT)			
7. Was/will there be corrective action for this event?(PDCORRNY)		1-Yes	
a. If "No", describe why corrective action was not or will not be	U 0-No	1-Yes	
taken:(PDNOCRSP)			
h If "Vee" which of the following corrective estimateurs taken (as)	last all that	f annie)	
<ul> <li>b. If "Yes", which of the following corrective actions were taken: (sel</li> <li>1. Participant consent/reconsent was/will be obtained: (PDCACNST)</li> </ul>	_	1-Yes	
<ol><li>Research staff corrected/will correct error(s) and/or completed/will complete document(s):(PDCASTCR)</li></ol>		☐ 1-Yes	
<ul> <li>3. Participant corrected/will correct error(s) and/or completed/will complete document(s):(PDCAPTCR)</li> <li>4. Document(s) was/will be moved to correct file location(s):</li> </ul>	□ 0-N0		
(PDCADCMV)	☐ 0-No	1-Yes	
5. Participant was/will be withdrawn from study:(PDCAPTWD)	O-No	☐ 1-Yes	
6. Study drug administration was/will be halted:(PDCADGSP)	O-No	☐ 1-Yes	
7. Study assessment was/will be performed or repeated: (PDCAASAD)		☐ 1-Yes	
8. Other:(PDCAOTHR)	□ 0-No	1-Yes	
1.1. If "Other", specify:(PDCAOTSP)			
<ul> <li>c. As needed or requested, provide additional details about the corrective action plan: (PDCAPSP)</li> </ul>			
8. Brief description of the plan to prevent recurrence: (select all that apa. Complete local retraining: (PDPLPTRN)			
1. If "Complete location retraining", specify:(PDPLPSP)			
b. Revise local SOP(s):(PDPLPRV)	☐ 0-No	1-Yes	
c. Recalibrate/fix or replace faulty equipment/supplies:(PDPLPEQ)	_	1-Yes	
d. Remove and/or replace incorrect/outdated document(s) from file(s)(PDPLPDOC)	☐ 0-No	☐ 1-Yes	
e. No site action needed:(PDPLPNAN)		1-Yes	
f. Other:(PDPLPOTH)	☐ 0-No	1-Yes	
1. If "Other", specify:(PDPLPOSP)	1		

9. Is this deviation reportable to your IRB?(PDIRBREP)	□ 0-No □ 1-Yes
10. Is this deviation reportable to the IRB of record?(PDIRBR	REP) 0-No 1-Yes
<ul> <li>a. If "Yes", will the IRB be notified at the time of continuing (PDIRBCON)</li> </ul>	g review?
b. If "Yes", date of planned submission:(PDIRBPDT)	(mm/dd/yyyy)
c. If "No", date of actual submission:(PDIRBADT)	(mm/dd/yyyy)
Comments:(PDVCOMM)	
	//

## 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

04-4th Protocol Deviation of the day

05-5th Protocol Deviation of the day

06-6th Protocol Deviation of the day

07-7th Protocol Deviation of the day

08-8th Protocol Deviation of the day

09-9th Protocol Deviation of the day

10-10th Protocol Deviation of the day

#### If "Yes", how many participants?

06-6

07-7

8-80

09-9

10-10

11-11

12-12

13-13

14-14

15-15

16-16 17-17

.. ..

18-18

19-19

20-20

#### **Deviation type:**

01Z--- Other informed consent/assent procedures issues (specify)

020-INCLUSION/EXCLUSION CRITERIA

02A--- Ineligible participant enrolled/inclusion/exclusion criteria not met or eligibility not fully ass

02B--- Ineligible participant randomized/inclusion/exclusion criteria not met or eligibility not fully a

02Z--- Other inclusion/exclusion criteria issues (specify)

040-LABORATORY ASSESSMENTS

04Y--- Other laboratory assessment issues - Minor (specify)

04Z--- Other laboratory assessments issues - Major (specify)

050-STUDY PROCEDURES/ASSESSMENTS

05A--- Study assessment/procedures not followed in accordance with study protocol

05B--- Inappropriate unblinding

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

06D--- AE/SAE not elicited, observed and/or documented as per protocol

06E--- Safety assessment (e.g., labs, ECG, clinical referral to care) not conducted per protocol

06Z--- Other adverse events issues (specify)

070-RANDOMIZATION PROCEDURES

07A--- Stratification error

07Z--- Other randomization procedures issues (specify)

080-STUDY MEDICATION MANAGEMENT

08A--- Medication not dispensed/administered in accordance with the study protocol

08B--- Participant use of protocol prohibited medication

08Z--- Other study medication management issues (specify)

090-STUDY BEHAVIORAL INTERVENTION

09A--- Study behavioral intervention was not provided/performed as per protocol

09Z--- Other study behavioral intervention issues (specify)

100-STUDY DEVICES

10A--- Study devices dispensed to ineligible participant

10Z--- Other study devices issues (specify)

110-SAFETY EVENT

11A--- Safety event not reported

11B--- Safety event reported out of protocol specified reporting timeframe

11C--- Safety event not elicited, observed and/or documented as per protocol

11D--- Safety event assessment not conducted per protocol

11Z--- Other safety event issues (specify)

990-OTHER SIGNIFICANT DEVIATIONS

99A--- Destruction of study materials without prior authorization from sponsor

99B--- Breach of Confidentiality

99Y--- Other significant deviations issues - Minor (specify)

99Z--- Other significant deviations issues - Major (specify)



- (\$sitecode)

Version: 6.00; 01-20-23

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### Recruitment Log (RCL)

#### Week start date (WEEKSTDT):

Use this log to document all recruitment efforts for the study. The RC/RA should only record initial contact with patients; do not include follow-up recruitment efforts to the same patient. Each box represents one day of recruitment for each mode of contact (i.e., letter, text message, patient portal message, etc.) in aggregate form. The log should be entered into eClinical on a weekly basis.

Date	Total Number of	Clinic	Clinic	Clinic	Mode of Contact	Comments
	Unique Patients Contacted (aggregate #)					
(RCDATE01) (mm/dd/yyyy)	(RCNPAT01) (xxxx)	(RCCLIN01)  01-Clinic  1 02- Clinic 2	(RCCLIN01)  01-Clinic  1 02- Clinic 2 03-Clinic 3	(RCCLIN01)	(RCMODE01)	(RCCOMM01)
(RCDATE02) (mm/dd/yyyy)	(RCNPAT02) (XXXX)	(RCCLIN02)  01-Clinic  1 02- Clinic 2	(RCCLIN02)  01-Clinic  1 02- Clinic 2 03-Clinic 3	(RCCLIN02)	(RCMODE02)	(RCCOMM02)
(RCDATE03) (mm/dd/yyyy)	(RCNPAT03) (XXXX)	(RCCLIN03)  01-Clinic  1 02- Clinic 2	(RCCLIN03)  01-Clinic  1 02- Clinic 2 03-Clinic 3	(RCCLIN03)	(RCMODE03)	(RCCOMM03)
(RCDATE04) (mm/dd/yyyy)	(RCNPAT04) (XXXX)	(RCCLIN04)  01-Clinic  1 02- Clinic 2	(RCCLIN04)  01-Clinic  02- Clinic 2  03-Clinic 3	(RCCLIN04)	(RCMODE04)	(RCCOMM04)
(RCDATE05) (mm/dd/yyyy)	(RCNPAT05) (XXXX)	(RCCLIN05)  01-Clinic  1 02- Clinic 2	(RCCLIN05)  01-Clinic  1 02- Clinic 2 03-Clinic 3	(RCCLIN05)	(RCMODE05)	(RCCOMM05)
(RCDATE06) (mm/dd/yyyy)	(RCNPAT06) (XXXX)	(RCCLIN06)  01-Clinic  1 02- Clinic 2	(RCCLIN06)  01-Clinic 1 02- Clinic 2 03-Clinic 3	(RCCLIN06)	(RCMODE06)	(RCCOMM06)
(RCDATE07) (mm/dd/yyyy)	(RCNPAT07) (xxxx)	(RCCLIN07)  01-Clinic  1 02- Clinic 2	(RCCLIN07)  01-Clinic  1 02- Clinic 2 03-Clinic 3	(RCCLIN07)  01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	(RCCOMM07)

(RCDATE08)	(RCNPAT08)	(RCCLIN08)	(RCCLIN08)	(RCCLIN08)	(RCMODE08)	(RCCOMM08)
(mm/dd/yyyy)	(xxxx)	01-Clinic 1 02- Clinic 2	01-Clinic 1 02- Clinic 2 03-Clinic 3	01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	//
(RCDATE09)	(RCNPAT09)	(RCCLIN09)	(RCCLIN09)	(RCCLIN09)	(RCMODE09)	(RCCOMM09)
(mm/dd/yyyy)	(xxxx)	1 02- Clinic 2	1 02- Clinic 2 03-Clinic 3	01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	
(RCDATE10)	(RCNPAT10)	(RCCLIN10)	(RCCLIN10)	(RCCLIN10)	(RCMODE10)	(RCCOMM10)
(mm/dd/yyyy)	(xxxx)	01-Clinic 1 02- Clinic 2	01-Clinic 1 02- Clinic 2 03-Clinic 3	01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	
(RCDATE11)	(RCNPAT11)	(RCCLIN11)	(RCCLIN11)	(RCCLIN11)	(RCMODE11)	(RCCOMM11)
(mm/dd/yyyy)	(xxxx)	01-Clinic 1 02- Clinic 2	01-Clinic 1 02- Clinic 2 03-Clinic 3	01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	
(RCDATE12)	(RCNPAT12)	(RCCLIN12)	(RCCLIN12)	(RCCLIN12)	(RCMODE12)	(RCCOMM12)
(mm/dd/yyyy)	(xxxx)	01-Clinic 1 02- Clinic 2	01-Clinic 1 02- Clinic 2 03-Clinic 3	01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	
(RCDATE13)	(RCNPAT13)	(RCCLIN13)	(RCCLIN13)	(RCCLIN13)	(RCMODE13)	(RCCOMM13)
(mm/dd/yyyy)	(xxxx)	01-Clinic 1 02- Clinic 2	01-Clinic 1 02- Clinic 2 03-Clinic 3	01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	
(RCDATE14)	(RCNPAT14)	(RCCLIN14)	(RCCLIN14)	(RCCLIN14)	(RCMODE14)	(RCCOMM14)
(mm/dd/yyyy)	(xxxx)	01-Clinic 1 02- Clinic 2	01-Clinic 1 02- Clinic 2 03-Clinic 3	01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	
(RCDATE15) [mm/dd/yyyy)	(RCNPAT15) (xxxx)	(RCCLIN15)  01-Clinic  1 02- Clinic 2	(RCCLIN15)  01-Clinic  1 02- Clinic 2 03-Clinic 3	(RCCLIN15) 01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	(RCCOMM15)

(RCDATE16) (mm/dd/yyyy)	(RCNPAT16) (xxxx)	(RCCLIN16)  01-Clinic  1 02- Clinic 2	(RCCLIN16)  01-Clinic  1 02- Clinic 2 03-Clinic 3	(RCCLIN16)  01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	(RCCOMM16)
(RCDATE17) (mm/dd/yyyy)	(RCNPAT17) (XXXX)	(RCCLIN17)  01-Clinic  1 02- Clinic 2	(RCCLIN17)  01-Clinic  1 02- Clinic 2 03-Clinic 3	(RCCLIN17)  01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	(RCCOMM17)
(RCDATE18) (mm/dd/yyyy)	(RCNPAT18) (XXXX)	(RCCLIN18)  01-Clinic  1 02- Clinic 2	(RCCLIN18)  01-Clinic  1 02- Clinic 2 03-Clinic 3	(RCCLIN18) 01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	(RCCOMM18)
(RCDATE19) (mm/dd/yyyy)	(RCNPAT19) (xxxx)	(RCCLIN19)  01-Clinic  1 02- Clinic 2	(RCCLIN19)  01-Clinic 1 02- Clinic 2 03-Clinic 3	(RCCLIN19) 01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	(RCCOMM19)
(RCDATE20) (mm/dd/yyyy)	(RCNPAT20) (xxxx)	(RCCLIN20)  01-Clinic  1 02- Clinic 2	(RCCLIN20)  01-Clinic  1 02- Clinic 2 03-Clinic 3	(RCCLIN20)  01-Clinic 1 02-Clinic 2 03-Clinic 3 04-Clinic 4 05-Clinic 5 06-Clinic 6	01-Patient portal message 02-Letter 03-Text message 04-Phone call 05-Approach in clinic	(RCCOMM20)
Comments:(RCLCC	DMM)					