Patient-Prescriber Agreement Form

My Decision about Taking a TIRF Medicine

- This form records your decision about taking a Transmucosal Immediate Release
 Fentanyl medicine that has serious risks. These drugs are also called TIRF medicines.
- Your prescriber must explain the drug's benefits and risks so you understand and can make an informed decision. Think carefully about the possible harms.
- Ask questions until you are comfortable deciding about the drug.
- This form will go in your medical records. Your prescriber will also give you a copy.

Patient

TIRF Medicines can cause you to stop breathing - which can lead to death.

Safety Rules for TIRF Medicines

You have agreed to take a TIRF Medicine and follow all the safety rules to make it less likely you or others will experience serious harm.

- I can only use this medicine if I am regularly using another opioid, around-the-clock, for constant pain.
- 2. If I stop taking my around-the-clock opioid pain medicine, I must stop taking my TIRF medicine.
- 3. I understand how I should take this TIRF medicine, including how much I can take and how often I can take it. If my prescriber prescribes a different TIRF medicine for me, I will make sure I understand how to take the new TIRF medicine.
- 4. TIRF medicines can cause breathing to stop, which can lead to death.

 This risk is higher if I do not take my TIRF medicine exactly as my prescriber has directed me.
- 5. I agree to contact my prescriber if my TIRF medicine does not relieve my pain. I will not change the dose

- of my TIRF medicine myself or take it more often than my prescriber has directed.
- 6. I agree that I will never give my TIRF medicine to anyone else, even if they have the same symptoms.
 - My TIRF medicine could cause harm to others or even death.
 A dose that is okay for me could cause an overdose and death for someone else.
- 7. I will store my TIRF medicine in a safe place away from children and teenagers. Accidental use by a child, or anyone for whom it was not prescribed can cause death.
- 8. I have been told how to properly dispose of my partially used or unneeded TIRF medicine remaining from my prescription. I will dispose

- of my TIRF medicine properly as soon as I no longer need it.
- 9. I understand that selling or giving away my TIRF medicine is against the law.

provide will be stored in a secure and private database. My information may be shared with the U.S. Food and Drug Administration (FDA) as necessary.

Patient	11. I understand my TIRF medicine is
10. My personal information will be shared to enroll me into and manage the TIRF REMS*. The TIRF REMS may contact me by phone, mail or email. The information I	only available at pharmacies that are part of the TIRF REMS program. My prescriber will let me know the pharmacy closest to my home where I can have my TIRF medicine prescription filled.
If you have any questions about your TIRF medic	cine or these safety rules or how to follow
them, contact your prescriber as soon as possibl	
Name (print)	
Signature	Date
Date of Birth (MM/DD/YYYY) State ZIP Code Phone Number Patient Representative (if required) Signature Date	
First Name Las Relationship to Patient	st Name

*TIRF REMS

The patient is receiving this form because the drug is part of an FDA program called the <u>Risk Evaluation</u> and <u>Mitigation Strategy</u> (REMS). The FDA is the federal agency that makes sure that drugs marketed in the United States are safe and effective. For certain prescription drugs, drug companies and prescribers must take extra steps, such as counseling patients about serious risks, to make sure the benefits of using the drug are more than the risks. FDA must approve these steps as part of a REMS. For questions or more information about this drug's specific REMS, please call 1-800-XXX-XXXX or visit

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