

## Adverse Events of Special Interest Reporting Form

**INSTRUCTIONS:**

- **Adverse events related to accidental exposure, misuse, abuse, addiction, overdose or other serious adverse events must be reported to the TIRF REMS.**
- This form must be completed to report an adverse event of special interest to the TIRF REMS for any patient taking a TIRF medicine.
- For real-time processing, complete this form online at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) by logging on, selecting the patient, and reporting the Adverse Event of Special Interest.
- The form may also be faxed to the program at 1-855-474-3062. If faxed, allow one (1) business day for processing.

\*Indicates required field

1 Patient Information (please print)				
First Name*	M.I.	Last Name*	Date of Birth* (MM/DD/YYYY)	Zip Code*
TIRF Product Name (if known)		Strength (if known)	Dose (if known)	Frequency (if known)
2 Reporter Information (please print)				
First Name*	M.I.	Last Name*	Individual NPI # (if applicable)	
Phone*		Extension*	Fax*	
Email Address*			Best Time to Contact: <input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening	
3 Adverse Events of Special Interest				
<b>Adverse events related to accidental exposure, misuse, abuse, addiction, overdose or other serious adverse events must be reported to the TIRF REMS.</b> <b>If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.</b> <b>Check all that apply below</b>				
<input type="checkbox"/> Experienced an overdose of their TIRF medicine (Overdose - ingestion of an excessive amount of drug that is considered lethal or toxic, either intentionally or accidentally)				
<input type="checkbox"/> Shown signs or symptoms of addiction to their TIRF medicine (Addiction - a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance. Signs and symptoms include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal)				
<input type="checkbox"/> Misused or been suspected of misusing their TIRF medicine (Misuse - the use of a medicinal product without a prescription or in a manner other than as directed by a physician, including use without a prescription of one's own; use in greater amounts to feel euphoria (i.e. to get high), more often, or for a period longer than prescribed; or use in any other way not directed by the prescribing physician)				
<input type="checkbox"/> Abused or been suspected of abusing their TIRF medicine (Abuse - intentional non-therapeutic use of a medicinal product, even once, for its rewarding psychological or physiological or euphoric effect, and often associated with physical dependence)				
<input type="checkbox"/> Someone else has been accidentally exposed to the patient's TIRF medicine (Accidental exposure - unintended exposure of a medicinal product to someone other than to whom it was prescribed)				
<input type="checkbox"/> Another serious adverse event (Serious Adverse Event - any adverse event at any dose that results in death, is life-threatening, requires inpatient hospitalization, or causes prolongation of existing hospitalization)				
4 Reporter Signature				
Reporter Signature*:				Date*:
Complete this form online at <a href="http://www.TIRFREMSaccess.com">www.TIRFREMSaccess.com</a> or fax the completed form to 1-855-474-3062.				

Please visit [TIRFREMSaccess.com](http://TIRFREMSaccess.com) or call 1-866-822-1483 for more information about the TIRF REMS.