CLEAR FORM

Letairis REMS Patient Enrollment and Consent Form

Complete and submit the form online at www.letairisrems.com or fax this form to 1-888-882-4035.

1 Patient Information (PLEASE PRINT)

First Name:	Middle Initial:	Last Name:		
Address:		City:	State:	ZIP:

Birthdate: / /	Gender: ☐ M ☐ F	Preferred Time to Contact: ☐ Day ☐ Evening	Home Phone: ( ) –	Mobile Phone: ( ) –	E-mail:
Alternate Contact Name:			Alternate Phone: ( ) –	Relationship:	

2 Female Patient Agreement

For All Females: I acknowledge that I have been counseled that Letairis is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS). I have read the *Letairis REMS Program Guide for Female Patients.* Permission to share personal and health information: I authorize my healthcare providers and pharmacies to share my personal and health information with Gilead Sciences, Inc., and its agents ("Gilead"), in order for Gilead to use and disclose my information to administer the Letairis REMS Program. Gilead agrees to protect my information and to use and share it only to administer the Letairis REMS program.

For Females Who Can Get Pregnant: I acknowledge that I have been counseled on the risks of Letairis, including the risk of serious birth defects. I have read the *Letairis REMS Program Guide for Female Patients.* I understand that I will be contacted by Gilead and/or its agents and contractors to receive counseling on the risk of serious birth defects and the importance of not becoming pregnant, ensure that I have completed pregnancy testing before I start Letairis, monthly before each refill, and for 1 month after stopping Letairis, and obtain information about my pregnancy, if I become pregnant.

For Pre-Pubertal Females: I acknowledge that I have been counseled on the risks of Letairis, including the risk of serious birth defects, and that I have read the *Letairis REMS Program Guide for Female Patients.* Parent or guardian must sign below.

REQUIRED FOR ALL FEMALE PATIENTS	Patient or Parent/Guardian Signature: X	Date: / /

3 Prescriber Information (PLEASE PRINT)

First Name:	Last Name:	State License #:	
Address:	City:	State:	ZIP:

Phone: ( ) –	Fax: ( ) –	NPI #:
Office Contact (First and Last Name):	E-mail:	

4 Statement of Medical Necessity

Diagnosis: Pulmonary Arterial Hypertension (The following list is not to suggest approved uses or indications. Please select one category below.)

☐ Primary Pulmonary Hypertension
☐ Pulmonary Hypertension, Secondary
☐ Pulmonary Heart Disease, Unspecified
☐ Other _____

5 Prescriber Authorization (REQUIRED FOR ALL FEMALE PATIENTS)

REQUIRED FOR ALL FEMALE PATIENTS

Only 1 box should be checked. For female patients, please indicate the patient's current reproductive status below. (Please see definitions of these terms below)

Female of Reproductive Potential
Has a negative pregnancy test been confirmed prior to prescribing Letairis? ☐ Yes ☐ No

OR

Female of Non-Reproductive Potential (choose one below)
☐ Pre-Pubertal Female ☐ Post-Menopausal Female
☐ Other medical reasons for permanent, irreversible infertility

I certify that for female patients, I have provided the appropriate counseling and Letairis REMS materials, and I will continue to fulfill my obligations under the Letairis REMS Program.

REQUIRED FOR ALL PRESCRIBERS	Prescriber Signature: X	Date: / /

Definitions:

Females of Reproductive Potential
- Females of Reproductive Potential include girls who have entered puberty and all women who have a uterus and have not passed through Menopause (as defined below).
- For the purposes of REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).

Females of Non-Reproductive Potential
- Pre-Pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- Post-Menopausal Females: Females who have passed through Menopause (as defined below)
- Other medical reasons for permanent, irreversible infertility

Menopause
Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy.

Prescriber obligations under the Letairis REMS Program

For All Females
- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that Letairis is available only through a restricted distribution program under an FDA-required REMS.
- I will evaluate the patient and agree to document any change in reproductive potential status by submitting a *Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form* within 10 business days of becoming aware of the change.

For Females of Reproductive Potential
- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of Letairis, including the risk of serious birth defects, and that I have reviewed the *Letairis REMS Program Guide for Female Patients* with the patient (and parent/guardian when appropriate).
- I will order and review pregnancy tests prior to initiation of Letairis treatment, monthly during treatment, and for 1 month after stopping treatment in accordance with the Letairis REMS Program.

For Pre-Pubertal Females
- I acknowledge that I have counseled the patient and parent/guardian on the risks of Letairis, including the risk of serious birth defects, and that I have reviewed the *Letairis REMS Program Guide for Female Patients* with the patient and parent/guardian.
- I will evaluate the patient's reproductive potential status, verify reproductive potential status annually for Pre-Pubertal Females who are at least 8 years of age and older, and agree to report any change in reproductive potential status on a *Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form* within 10 business days of becoming aware of the change.

6 Complete and submit the form online at www.letairisrems.com or fax this form to 1-888-882-4035.

Please visit **www.letairisrems.com** or call **1-866-664-5327** for more information about the Letairis REMS Program.
Please see accompanying patient Medication Guide and Prescribing Information, including **BOXED WARNING**.
This form is part of an FDA-approved REMS.