

## AE Reporting System (AERS) Start-up Guide

The Adverse Events Reporting System (AERS) enables Investigators and their research associates to streamline AE submissions to the USF Institutional Review Board (IRB). The following table summarizes key system features and their benefits:

System Features	Direct Benefits
Complete AE Forms On-line	Increases efficiency in form completion
Submit AE Reports On-line	Aids compliance with AE reporting deadlines; Reduces paper
Track AE Reports Submitted	Provides real-time snapshots of submitted AEs; Increases efficiency and effectiveness of AE summary reporting for Continuing Review and overall AE risk assessment

Principal Investigators (PIs) can designate individuals (“Coordinators/Preparers”) to prepare AE forms on-line for the PI to review; however, only PIs can submit the AE reports to the USF IRB. To illustrate, a PI-designated Study Coordinator prepares an AE form on-line, she/he then notifies the PI that the AE form is ready for review. After reviewing and editing (if needed), the PI clicks a button within the AE Reporting System to submit the final AE Report on-line.

### Getting Started

#### **Step 1 Register On-line**

*Principal Investigators and Coordinators/Preparers*

1. Click on the [Adverse Events Reporting System](http://www.research.usf.edu/cs/irb.htm) link on the IRB Web Site located at <http://www.research.usf.edu/cs/irb.htm>.
2. Click the **register** link on the **User Login** screen.
3. In the boxes for Packet-key, type **9D9D9D** and click **Continue**.
4. Type in your contact information and click **Create**.
5. The system will display your unique User ID and Password. Print this window and save it in a safe place.

#### **Step 2 Submit User License Agreement**

*Principal Investigators only; these are not needed for Coordinators/Preparers*

1. Submit a complete, signed, dated, and original User License Agreement to the Division of Research Compliance. Please retain a copy for your records.
2. Receive e-mail notification that the Division of Research Compliance has verified the Principal Investigator’s user information and activated the PI’s User ID and Password.

### Instruction Manual

The AERS User's Manual is available on-line via the Division of Research Compliance IRB Web Site at <http://www.research.usf.edu/cs/aers.htm>. The manual provides step-by-step instructions for registering; for preparing, submitting, viewing, and tracking AEs reported to the IRB; and for managing your User Account information in the new system.

### For More Information

Please contact the AERS Project Manager, via phone at (813) 974-9343 or via e-mail at [ae@research.usf.edu](mailto:ae@research.usf.edu).