

Office of Research Compliance
WIRB Off Site Adverse Event/IND Safety Reporting

June 8, 2007

I: OBJECTIVE

Principal Investigator/Coordinator procedures for reporting of Off Site Adverse Event (A/E) reports, also known as Investigational New Drug (IND) Safety Reports, for sponsored clinical trials reviewed and approved by Western IRB (WIRB).

II: WIRB RESPONSIBILITIES

The WIRB is the agency responsible for review, approval and management of Sponsored Multi-Center clinical trials for Investigators of Drexel University College of Medicine and operates under our Federal Wide Assurance number, 00005917. In order to remain in compliance with all Federal, State, Local, and University regulations and polices, the following instructions describes the process of reporting and managing Off Site Adverse Events (A/E or IND) notices.

III: PI or COORDINATOR RESPONSIBILITIES

Upon receipt of an Off Site Adverse Event report from the trial sponsor, the PI/Coordinator should initiate the following:

1. Contact the WIRB Client Services attendant by email: clientservices@wirb.com or by telephone at 1-800-562-4789.
2. Provide the attendant with the following information to determine if WIRB is currently in possession of the report as the A/E notice may have been sent directly to WIRB by the sponsor.
 - a. Title and protocol number as provided by sponsor.
 - b. A/E incident report number and date of incident.

IV: PROCEDURES WHEN WIRB IS ALREADY IN POSSESSION OF A/E REPORT FROM SPONSOR

3. If WIRB has the Off Site A/E report on file the PI/Coordinator will email (clientservices@wirb.com) or FAX (1-360-252-2498) to Client Services the following information in memo format:
 - a. Date of communication
 - b. PI Name and contact information
 - c. Study title and number
 - d. WIRB Protocol number
 - e. Sponsor name
 - f. A/E (IND) identification number
 - g. An acknowledgement that the PI/Coordinator has this specific A/E on file in the regulatory binder
 - f. Forward a copy of these communications to the Drexel University Office of Research Compliance (ORC) to be retained on file by the ORC coordinator

V: PROCEDURES WHEN WIRB IS NOT IN POSSESSION OF AE REPORT

If WIRB Client Services indicates that they do NOT have this specific A/E report in their possession, the PI/Coordinator will forward the following information via courier (UPS), mail service, or FAX to WIRB Client Services. The packet that is forwarded to WIRB must include:

- a. Memo to file in the format described above
- b. A copy of the cover letter as provided by the sponsor
- c. A copy of the incident(s) report of the off site Adverse Event
- d. The PI/Coordinator will retain a copy of the original documents for filing in the regulatory binder
- e. Also note, some sponsors may request a direct communication/memo to file from the PI/Coordinator to the sponsor that the A/E or IND in question has in fact been sent to the reviewing IRB.
- f. Forward a copy of this material to the Drexel University Office of Research Compliance to be retained on file by the ORC coordinator.

VI: ORC HELP DESK FOR ASSISTANCE

If you should have any further questions or are in need of clarity please do not hesitate to contact the Office of Research Compliance at 215-762-3453.

Please ask for Jack Medendorp to obtain the necessary assistance.