

Emergency Action Plan

By Norman M. Goldfarb

Every organization involved in clinical research should have an emergency action plan. The following template is a good starting point. Emergencies may include hurricanes, fires, floods, key personnel illnesses, severe allergic reactions to study drug, etc. An actual EAP will include details. For example, if there is a natural gas shut-off valve, specify its location, the location of a suitable wrench, instructions for shutting the valve, and personnel authorized to turn-off the gas.

PURPOSE AND SCOPE

1. This Emergency Action Plan (EAP) describes [our] requirements for preparing for and responding to emergencies.
2. This EAP applies to all personnel.

REQUIREMENTS

1. Make basic preparations.
 - a. Designate emergency management personnel.
 - b. Make first aid kits, flashlights and fire extinguishers available.
 - c. Train personnel, first aid, use of fire extinguishers, location of utility switches and valves, and emergency action plan.
 - d. Store a current back-up copy of all electronic records offsite.
 - e. Store a copy of the EAP in multiple secure offsite locations.
 - f. Store a list of personnel and contact information in multiple secure offsite locations, including backup contact information such as family members.
 - g. Store contact information for study subjects in multiple secure offsite locations, including backup contact information such as family members.
 - h. Post emergency contact information online.
 - i. Create checklists.
 - j. Identify rendezvous locations.
2. Develop detailed plans for specific types of emergencies.
 - a. Identify potential emergencies (e.g., fire, flood, earthquake), and develop separate EAP for each type of emergency.
 - b. Identify points of vulnerability (e.g., records storage, computers, telephone communications) and develop separate EAP for protecting each point of vulnerability.
 - c. Identify scenarios (e.g., where a fire starts or when a water pipe breaks); fine tune EAP accordingly.
 - d. Allocate preparation resources based on the severity and likelihood of damages to each point of vulnerability in each type of emergency in each scenario.

3. If an emergency occurs, take the following steps, in this basic order of priority, as safe and appropriate.
 - a. Use good judgment and common sense.
 - b. Call 911.
 - c. Administer first aid (if properly trained and certified).
 - d. Evacuate and secure facilities; meet at best available rendezvous point, if possible, for a headcount and further instructions.
 - e. Extinguish fires.
 - f. Protect property, giving priority to computer and paper files and records.
 - g. Turn off gas, electricity and water.
 - h. Inform all personnel of emergency status and plans.
 - i. Inform sponsors and subjects that emergency occurred and plan of action.
 - j. Return to normal operations when possible.
 - k. File insurance claims and police reports.
 - l. Document the emergency and response with narrative of events, damaged property and material inventory, photographs, insurance claims, police and fire department reports, and news accounts.
 - m. Review emergency and response to improve EAP.

Norman M. Goldfarb is Managing Partner of First Clinical Research, a provider of a clinical research best practices consulting, training, implementation and research services. Contact him at (650) 465-0119 or ngoldfarb@firstclinical.com.