

	FURTHER INVESTIGATOR RESPONSIBILITIES			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	5.01	02.07.2020	5.25	03.25.2019

The researcher provides evidence of his or her qualifications through up-to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB, or the regulatory authority.

The researcher is familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the sponsor.

The researcher ensures the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.

Description of Researcher Responsibilities when following Department of Education regulations:

1. All instructional material--including teachers' manuals, films, tapes, or other supplementary instructional material--which will be used in connection with any research or experimentation program or project, must be available for inspection by the parents or guardians of the children engaged in such research.
2. Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.
3. Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

Reporting to the Sponsor, Regulatory Authority and the IRB:

The researcher reports all serious adverse events (SAEs) to the sponsor except for those SAEs that the protocol or other document (e.g., investigator's brochure) identifies as not needing immediate reporting. The researcher follows regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the IRB.

The researcher reports adverse events or laboratory abnormalities identified in the protocol as critical to safety evaluations to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

For reported deaths, the researcher supplies the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).

The researcher provides written reports to the sponsor, the IRB, and, where applicable, the organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.

If the researcher terminates or suspends a clinical trial without prior agreement of the sponsor, the researcher informs the organization, sponsor, and the IRB.

If the IRB terminates or suspends approval of the clinical trial, the researcher promptly notifies the sponsor.

Upon completion of the clinical trial, the researcher informs the organization, the IRB with a summary of the trial's outcome, and the regulatory authority with any reports required.