

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.003
<b>Effective Date:</b> 1/23/2006	<b>Page 1 of 2</b>	<b>Replaces Policy Dated:</b>
<b>Description:</b>	Definitions	

**Clinical investigation** means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical studies. The terms *research*, *clinical research*, *clinical study*, *study*, and *clinical investigation* are deemed to be synonymous...[\[21 CFR 56.102\(23\(c\)\)](#)].

**Guardian.** Nevada State Law [\(NRS 159.017\)](#) states: “Guardian” means any person appointed under this chapter as guardian of the person, of the estate, or of the person and estate for any other person, and includes an organization under NRS 662.245 and joint appointees. The term includes a special guardian. A guardian may not consent to the experimental treatment of a ward without approval of the court ([NRS 159.0805](#)).

**Human subject** means a living individual about whom an investigator conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject.

**Legally Authorized Representative** means that a judicial body has issued an order establishing jurisdiction to make healthcare decisions.

**Minor.** According to Nevada State Law, minors are persons under the age of eighteen [NRS 159.023](#). The general rule is that a person may consent for his or her own medical care at the age of eighteen. Certain statutes and case law, however, provide minors with majority status in some circumstances, for example: emancipated minor. [NRS 129.030](#)

**Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a

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medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects [\[45 CFR 46.102\(f\)\(1\)\(2\)\]](#).

**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [\[45 CFR 46.102\(d\)\]](#).

**Ward.** Nevada State Law [\(NRS 159.027\)](#) defines a ward as “any person for whom a guardian has been appointed”.