

Tip Sheet: Exemptions from IND Requirements for Clinical Research

(last updated 6/27/11)

Food and Drug Administration (FDA) regulations ([21CFR312.2](#)) exempt investigational uses of drugs and biologics from the requirements to submit an Investigational New Drug (IND) application to the FDA in the following circumstances:

“Off-Label” Use of FDA-Approved, US-Marketed Drugs

The investigational use of an approved, marketed drug product is exempt from IND requirements if *all* of the following apply:

- The new use ***is not intended to be reported to FDA*** to support of a new indication for use or to support any other significant change in the labeling for the drug/biologic;
- The new use ***is not intended to support a significant change in the advertising*** for the drug/biologic;
- The new use ***does not involve a change in the route of administration, dosage level, subject population or other factor that significantly increases the risks*** (or decreases the acceptability of the risks) associated with the use of the drug/biologic;
- The new use is conducted in compliance with the requirements for IRB review and informed consent;
- The new use is conducted in compliance with FDA requirements for promotion of investigational drugs ([21CFR312.7](#)); and
- The new use does not intend to invoke a waiver of informed consent for emergency research ([21CFR50.24](#))

IMPORTANT NOTE: IND requirements do ***not*** apply to the use of drugs in the practice of medicine for an unlabeled indication (sometimes referred to as “innovative use”) of a new drug product approved under part [21CFR314](#) or of a licensed biological product.

In Vitro Diagnostic Biological Products

A clinical investigation involving an ***in vitro diagnostic biological product*** (i.e., blood grouping serum, reagent red blood cells, or anti-human globulin) is exempt from IND requirements if (a) it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure **and** (b) it is shipped in compliance with [21CFR312.160](#).

In Vitro Tests and Laboratory Research Animals

A drug intended solely for tests ***in vitro or in laboratory research animals*** is exempt from IND requirements if shipped in accordance with [21CFR312.160](#).

Use of Placebos

A clinical investigation involving use of a placebo is exempt from IND requirements if the investigation does not otherwise require submission of an IND.