UCLA Research Administration
Human Research Protection Program

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.