IND EXEMPTIONS

Involving Drugs or Biologics

Exemption 1
Drug/Biologic US product

* Drug/biologic product lawfully marketed in US

* The investigation **is not** intended to be reported to FDA as a well controlled study in support of a **new indication** for use nor intended to be used to support any other **significant change in the labeling** for the drug/biologic.

* The investigation proposed **is not** intended to support a **significant change in the advertising** for the drug/ biologic

* The investigation **does not** involve a route of administration, dose, patient 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 investigation will be conducted in compliance with FDA regulations for the Protection of Human Subjects and Institutional Review Boards 21 CFR 50 & 56

* The investigation will be conducted in compliance with the FDA requirements for Promotion and Charging for Investigational Drugs 21 CFR 312.7

* The investigation is not intended to invoke an exception from informed consent requirements for planned emergency research under 21 CFR 50.24

Exemption 2
In Vitro Diagnostic Biological

* The clinical investigation is for an in vitro diagnostic biological product that involves one or more of the following:
  - Blood grouping serum
  - Reagent red blood cells
  - Anti-human globulin

* The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another medically established, diagnostic product or procedure.

  21 CFR 312.2(b)(2)

Exemption 3
In Vitro / Animal Lab Research

* The drug / biologic is intended solely for test in vitro or in laboratory research animals and is shipped in accordance with FDA Regulations for Drugs for investigational use in laboratory research animals or in vitro tests 21 CFR 312.160

Exemption 4
Placebo

* The clinical investigation involves the use of a placebo and the investigation does not otherwise require submission of an IND

Exemption 5
In Vivo Bioavailability or Bioequivalence

* Test product **does not** contain a **new chemical entity**"' as defined in 21 CFR 314.108(a) [** a drug that contains no active moiety that has been approved by FDA in any other application.

* The study **does not** involve a **radioactively labeled drug** product.

* The study **does not** involve a c**ytotoxic drug product.**
  The investigator will conduct a bioavailability or bioequivalence study in humans using a drug product that contains an already approved, non-new chemical entity and the study will involve a single dose in normal subject or patients where either the maximum single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approve new drug application or abbreviated new drug application.

* The investigator **will not** conduct a bioavailability or bioequivalence study in humans using a
  - **drug product that contains an already approved, non-new chemical entity**
  - the study will involve a **multiple-dose study in normal subjects**
  - or **patients where either the single or total daily dose exceeds that specified in the labeling** of the drug product that is the subject of an approved new drug application or abbreviated new drug application, or

* The investigator **will not** conduct a bioavailability or bioequivalence study in humans using a drug product that contains an already approved, non-new chemical entity and the study will involve a **multiple dose study on an extended release product on which no single dose study has been completed.**

  21 CFR 320.31