**Investigator Justification for IND Exemption**

**Background:** For FDA-regulated research studies using unapproved drugs, or using drugs outside of their approved indication, the regulations require a) an FDA-assigned IND number *or* b) a determination that the drug is *exempt* from IND requirements. If the FDA has not already made the latter determination, and the PI believes that the use is exempt from IND requirements, the PI will provide a justification to the IRB using this form. For more information, please see the [Emory Policies and Procedures](http://irb.emory.edu/documents/PoliciesAndProcedures.pdf) section 69. Note, this form should not be used for Vitamins or Supplements; please use the [Dietary Supplements and/or Medical Foods Used in Research](http://www.irb.emory.edu/documents/dietarysupplements-medicalfoods-research.docx) Form instead.

**Investigator:** Please complete this form if using a drug that is not FDA-approved for the indication described in the protocol, and you have determined that it meets the criteria for IND exemption (see below). If the overall investigation (which includes this drug) has an IND from the FDA, *this form is not needed*. Otherwise, upload this form in the “Drugs” section of the Smartform, under Question 3, for each applicable drug.

***NOTE****: Two or more drugs may only be listed on one form if the answers to all questions will be the* ***same*** *for all drugs.*

IRB number: Click or tap here to enter text.

PI Name: Click or tap here to enter text.

Study Title: Click or tap here to enter text.

Person completing this form: Click or tap here to enter text.

**Q1. List the name of the drug or drugs (if more than one, same answers must apply to all drugs):** Click or tap here to enter text.

**Q2. Is the drug FDA-approved for any indication?**

No  Yes

**If yes, proceed to Q3-A.**

If No, indicate if the following criteria apply, to complete this form (do not complete Q3-A,B). If none of these criteria apply,an Investigational New Drug (IND) submission may be required under part 312.

The research is a clinical investigation involving blood grouping serum, reagent red blood cells, or anti-human globulin, that (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 21 CFR 312.160.

The drug is intended solely for tests in vitro or in laboratory research animals that is shipped in accordance with 21 CFR 312.160.

For substance used as placebo: The research is a clinical investigation involving use of a placebo that does not otherwise require submission of an IND.

**Q3-A. Does the investigational use involve a route of administration or dosage level, or use in a subject population, or other factor that *significantly increases the risks (*or *decreases the acceptability of the risks*) associated with the use of the drug product**?

No  Yes  (If yes, an Investigational New Drug [IND] submission is required under part 312).

**If No, provide justification** that addresses risk to the intended population (e.g. is there information in the prescribing guidance that would contraindicate use in the proposed population? Citations from literature, clinical experience? Or, statement that use of drug(s) falls under FDA guidance for Cancer drugs at <https://www.fda.gov/media/71627/download>): Click or tap here to enter text.

**Q3-B. Indicate if the following criteria also apply (if any do not apply, use of drug is not exempt from IND):**

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.

If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.

The investigation is conducted in compliance with the requirements concerning the promotion and sale of drugs.

The investigation is conducted in compliance with the requirements for IRB review and informed consent.

The investigation does not intend to invoke 21 CFR 50.24, a waiver of informed consent in an emergency room setting.