



## EXEMPTION FROM IND REQUIREMENT CHECKLIST

Instructions for Investigators: If you think that your study falls into one of the following categories of research which are exempt from the requirements of 21 CFR Part 312, please check the appropriate box(es) and include a sentence explaining your determination. Sign the last page and send to the IBRA.

Instructions for the IBRA: When reviewing a protocol for a clinical trial for which an IND has not been obtained, complete every section of this form (designating N/A for sections that do not apply).

**Note: To be exempt under any category, all of the sub-requirements must apply.**

1. \_\_\_\_\_ (21 CFR 312.2(b)(1)):

- The clinical investigation involves a drug product lawfully marketed in the U.S.

YES  NO

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- The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use and is not intended to be used to support any other significant change in the labeling for the drug.

YES  NO

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- 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.

YES  NO

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- The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.

YES  NO

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- The investigation is conducted in compliance with the requirements for IRB review set forth in 21 CFR Part 56 and with the requirements for informed consent set forth in 21 CFR Part 50.

YES  NO

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- The investigation is conducted in compliance with 21 CFR 312.7 (regarding promotion and charging for investigational drugs).

YES  NO

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2. \_\_\_\_\_ (21 CFR 312.2(b)(2)):

- The clinical investigation involves one of the following in vitro diagnostic biological products:

blood grouping serum  reagent red blood cells  anti-human globulin

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

YES  NO

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- The product is shipped in accordance with 21 CFR Part 312.160.

YES  NO

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3. \_\_\_\_\_ (21 CFR 312.2(b)(3)): The investigation involves a drug intended solely for tests in vitro or in laboratory research animals and the drug is shipped in accordance with 21 CFR 312.160.

YES  NO

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4. \_\_\_\_\_ (21 CFR 312.2(b) (5)): The clinical investigation involves a placebo and the investigation does not otherwise require submission of an IND.

YES  NO

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Signature

Date