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| 21 CFR 312.2(b)(1) **To be exempt under this category, all of these sub-requirements must apply**: | |
| 1. The clinical investigation involves a drug product lawfully marketed in the U.S. | Yes |
| 1. 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 |
| 1. 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 |
| 1. 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. If oncologic therapy and IND is not necessary to permit deviations from the approved labeling to the extent that such changes are supported by the scientific literature and generally known clinical experience.   Please provide justification: | Yes |
| 1. The investigation is conducted in compliance with the requirements for IRB review set forth in21 CFR Part 56 and with the requirements for informed consent set forth in 21 CFR Part 50 | Yes |
| 1. The investigation is conducted in compliance with 21 CFR 312.7 (regarding promotion and charging for investigational drugs) | Yes |
| 21 CFR 312.2(b)(2) **To be exempt under this category, all of these sub-requirements must apply** | |
| 1. The clinical investigation involves one of the following in vitro diagnostic biological products (at least one box should be checked) | blood grouping serum  reagent red blood cells  anti-human globulin |
| 1. 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 |
| 1. The product is shipped in accordance with 21 CFR Part 312.160 | Yes |
| 21 CFR 312.2(b)(3) **To be exempt under this category, this sub-requirement must apply** | |
| 1. 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 |
| 21 CFR 312.2(b)(5) **To be exempt under this category, this sub-requirement must apply** | |
| 1. The clinical investigation involves a placebo **and** the investigation does not otherwise require submission of an IND (refer to the sections above) | Yes |

This checklist should be used to determine exemption of studies using lawfully marketed products in the U.S.