The purpose of this form is to determine whether use of the drug or biological product in this study is exempt from the FDA requirement to obtain an Investigational New Drug Application (IND) prior to beginning research. This form should be used when the Human Research is a ‘clinical investigation’ of a drug, which is “any experiment that involves a test article on one or more human subjects that either 1) requires FDA approval, or 2) is intended to be submitted to or inspected by the FDA for research or a marketing permit.”

* Drug: Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and is intended to affect the structure or any function of the body of man or other animals.

**Note: Drugs may be used in research but may not be the purpose of the investigation (e.g., as an adjunct to a standard procedure or test for screening).** **Information about these drugs must be included in the *IRB Application for Human Subjects Research*, so an assessment of risk and safety to subjects can be made. If the drug is not the purpose of the investigation, it is not necessary to complete this form.**

Instructions:

* Proceed through the form from the beginning and follow the listed flow instructions carefully.
* Complete a separate *Appendix for Drugs* for each drug or biologic listed in the eIRB system.

|  |
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| **Basic Information** |
| **Title of Study:** |       |
| **Short Title:** |       |
| **Principal Investigator Name:** |       |

|  |  |
| --- | --- |
| Section 1: General Information |  |
| Generic Name:       |
| Brand Name:       |
| Drug Manufacturer:       |
| Indications for Use:       |
| Dosage and Administration per Routine Care:       |
| Dosage and Administration in this Investigation (if different from Routine Care):       |
| Section 2: Regulatory Status Identification Identify the regulatory status of the agent(s) to be used in this study. Only ONE of the items listed below should apply to the agent under investigation |
| 1. The drug or biologic is approved by the FDA and will be used according to the FDA label. If Yes, STOP HERE and provide a copy of the FDA drug label in the eIRB system.  | **[ ]** Yes **[ ]** No |
| 2. The FDA has reviewed an IND submission and determined that an IND is not required.If Yes, STOP HERE and provide a copy of the FDA determination letter in the eIRB system.  | **[ ]** Yes **[ ]** No |
| 3. The investigation will be conducted under a valid IND number provided by the sponsor, CRO or FDA. If Yes, STOP HERE and provide a copy of the FDA determination letter in the eIRB system. Provide the IND Number:       | **[ ]** Yes **[ ]** No |
| 4. The investigation meets the exemption criteria under [21 CFR 312.2(b)(1)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.2). Note: To be exempt, a-e must be No. If a-e are all No, STOP HERE.  | **[ ]** Yes **[ ]** No |
| 1. Is the investigation intended to support FDA approval of a new indication or a significant change in the labeling of the agent?
 | **[ ]** Yes **[ ]** No |
| 1. Is the investigation intended to support a significant change in the advertising of the lawfully marketed agent?
 | **[ ]** Yes **[ ]** No |
| 1. Does the investigation involve a route of administration or dosage level or use in a patient population or other factor (e.g., formulation) that significantly increases the risks to subjects (or decreases the acceptability of the risks) associated with the use of the agent?
 | **[ ]** Yes **[ ]** No |
| 1. Is the investigation intended to promote or commercialize the investigational new agent (i.e., make promotional claims of safety or effectiveness)?
 | **[ ]** Yes **[ ]** No |
| 1. Does the study require any change in the approved formulation, dosage, or route of administration of the agent?
 | **[ ]** Yes **[ ]** No |
| 5. The clinical investigation involves one of the following in vitro diagnostic biological products under [21 CFR 312.2(b)(2))](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.2): anti-grouping serum, blood grouping serum, or reagent red blood cells. **Note: To be exempt, a-b must be Yes. If a-b are all Yes, STOP HERE.**  | **[ ]** Yes **[ ]** No |
| 1. Is the product intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure?
 | **[ ]** Yes **[ ]** No |
| 1. The product will be shipped in accordance with [21 CFR Part 312.160](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.160)?
 | **[ ]** Yes **[ ]** No |
| **Section 3: Agent Preparation and Control** |
| 1. Will the drug be kept in the investigational pharmacy?If No, answer a-g:1. Where will the agent be stored (include description, building, and room #)?
2. How will the agent be stored?
3. Is the proposed storage consistent with the recommended storage?
4. How will the storage conditions be recorded and maintained?
5. How will access to the agent be controlled and tracked?
6. Who will dispense the agent?
7. How will the agent be disposed?
 | **[ ]** Yes **[ ]** No |