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| **Principal Investigator:** | Click here to enter text. |
| **Study Title:** | Click here to enter text. |

Please complete if the research will involve drugs or biologics.

## Use of drugs or biologics

* 1. This research involves the following test articles (check all that apply and complete the appropriate sections below:

[ ] FDA-approved drug(s)/biologic(s)

[ ] Investigational (Non-FDA approved) drug(s)/biologic(s)
[ ] University lab/office

[ ] Other - Specify:

Click here to enter text.

* 1. Provide a plan for the storage, dispensing, handling, and disposal of investigational and FDA-approved drugs, devices and biologics. Where this is being done by the investigator, include a description of the procedures for inventory control and documentation.

Click here to enter text.

* 1. Does the sponsor of this research require compliance with the ICH-GCP guidelines?

 [ ] **Yes** [ ] **No**

If yes, the PI must review the document “International Conference on Harmonization (ICH) Good Clinical Practices (GCP), Applicability to Human Subjects Research” and affirm compliance.

## FDA-Approved Drugs/Biologics

* 1. List all of the FDA-approved drug(s)/biologic(s) to be used in the research:

Click here to enter text.

* 1. Doe the use of the text article involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability or the risks) associate with its use? [ ] **Yes** [ ] **No**

Click here to enter text.

NOTE: If yes, an IND may be required. Complete the following section for Investigational Drugs/Biologics.

## Investigational Drugs/Biologics

* 1. List all drugs/biologics used in this research. For each indicate:
		+ Name
		+ Chemical formula
		+ Dosage strength(s)
		+ Method/route of administration
		+ Mechanism of action
		+ Known drug interactions
		+ Manufacturer/Sponsor
		+ Name of supplier
		+ Location of supply

Click here to enter text.

* 1. Is there an IND for this research? [ ] **Yes** [ ] **No**

If yes, provide the IND Number(s)

Click here to enter text.

* 1. Provide evidence of the IND, i.e., a copy of the industry sponsored protocol with the IND number; or a letter from the FDA or industry sponsor setting forth the IND number.
	2. Who holds the IND?

[ ] Sponsor

[ ] Investigator

* 1. If the Investigator holds the IND, is the Investigator aware of the applicable FDA regulations and ensures that research is conducted according to the signed agreement and the approved protocol? [ ] **Yes** [ ] **No**
	2. If there is no IND, provide documentation establishing that the clinical investigation of the investigational drug at issue falls within one of the following categories:

[ ] The drug being used in the research is lawfully marketed in the United States and all of the following requirements are met:

[x] The research is not intended to support a significant change in the advertising for the product

[ ] The research does not involve a route of administration of dosage level, use in a subject population, or other factors that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product

[ ] The research is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively]

[ ] The research is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]

[ ] The research does not intend to invoke FDS regulations for planned emergency research [21 CFR 50.24]

[ ]  The research only involves one or more of the following: (a) Blood grouping serum, (b) Reagent red blood cells or (c) Anti-human globulin;

[ ]  For clinical investigations involving an in vitro diagnostic biological product, an IND is not necessary if, 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 FDA requirements at 21 CFR 312.1