Principal Investigator:

Study Title:

Please complete if the research will involve drugs or biologics.

1. Use of drugs or biologics

a. 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.

b. 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.

c. 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.

2. FDA-Approved Drugs/Biologics

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

Click here to enter text.

b. Does 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.

3. Investigational Drugs/Biologics

a. 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.

b. Is there an IND for this research? ☐**Yes** ☐**No**

If yes, provide the IND Number(s)

Click here to enter text.

d. Who holds the IND?

☐Sponsor

☐Investigator

e. 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**

f. 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:

☐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