Checklist for Sponsor Responsibilities

1. Maintaining an effective IND with respect to the investigations

☐ (a) Initial IND submission present (and contains the following):

☐ Is numbered 000

☐ Cover sheet (Form FDA 1571)

☐ FDA Form 3674

☐ Name, address, phone # of the Sponsor

☐ Date of application: ______________

☐ Name of investigational new drug: _______________________________

☐ Name and title of person responsible for review and evaluation of drug safety information:

☐ If any responsibilities will be transferred to a contract research organization (CRO), such transfers must be detailed in writing:

☐ Table of contents

☐ General investigational plan

☐ Summary of human experience with the drug

☐ If the drug has been withdrawn from investigation or marketing in any other country for reasons r/t safety and/or effectiveness

☐ IB

☐ Chemistry, Manufacturing, and Controls (CMC)

☐ Protocol(s)
Checklist for Sponsor Responsibilities

(b). Annual reports on the progress of the investigation **within ± 60 days of the anniversary date that the IND went into effect containing the following required elements:**

<table>
<thead>
<tr>
<th>Study title, purpose, patient population, and whether study has been completed</th>
<th>Annual Report #:</th>
<th>Date:</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Summary of study progress in the past year</th>
<th>Annual Report #:</th>
<th>Date:</th>
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</table>

<table>
<thead>
<tr>
<th>Total # of subject initially planned for inclusion; # entered into study to date, tabulated by age group, gender, and race; # completed as planned; # who dropped out for any reason</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<table>
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<tr>
<th>If study has been completed or interim results are available, these should be provided</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<table>
<thead>
<tr>
<th>Narrative or tabular summary of most frequent and most serious AEs by body system</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<table>
<thead>
<tr>
<th>Summary of all IND safety reports submitted in the past year</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<table>
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<tr>
<th>List of subject deaths to include cause of death</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<table>
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<tr>
<th>List of subjects who dropped out d/t AEs</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<table>
<thead>
<tr>
<th>Any information learned about the drug, dosing, bioavailability, etc.</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<tr>
<th>List of preclinical studies completed or in progress</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<tr>
<th>As applicable, any manufacturing or microbiological changes made during past year</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<table>
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<tr>
<th>Investigational plan for upcoming year</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<tr>
<th>As applicable, description of updates to IB</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<tr>
<th>For Phase 1 studies, description of protocol changes in previous year that were not previously reported to FDA via amendment</th>
<th>Annual Report #:</th>
<th>Date:</th>
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<th>Summary information of foreign marketing, including approval, withdrawal, or suspension</th>
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<th>Date:</th>
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(c) Amendments (note FDA Form 3674 as applicable)

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<td>Reactivation</td>
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<td>Development Safety Update (DSUR)</td>
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**Protocol Amendments**
- New Protocol
- Change in Protocol
- New investigator
- PMR/PMC approval

**Information Amendments**
- Chem/Microbio
- Pharm/Tox.
- Clinical
- Clin. Pharm.
- Stats

**Request for**
- Meeting
- Proprietary Name Review
- Special Prot. Assessment
- Formal Dispute

**IND Safety Report**
- Initial Written Report
- Follow-up to Written Report

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2. Selection of qualified investigators

The following are present for each site investigator:

☐ Signed Form FDA 1572 (Investigator Agreement)

☐ CV/biosketch/professional license

☐ Written disclosure of any financial conflicts of interest (Form FDA 3454 or 3455)

☐ Clinical protocol to be used and approved by the investigator’s institution

Comments:

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3. Ensuring proper monitoring of investigations

☐ Select a monitor qualified by training and experience to monitor the progress of all investigations conducted under its IND

☐ Have a documented and adequate monitoring plan, including the review and evaluation of the data and drug safety and effectiveness

☐ Monitoring reports

Comments:

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4. Promptly reporting to FDA and participating investigators

Provide both the FDA and investigators with the following:

☐ Current Investigator’s Brochure -
   *This must be provided to all participating investigators prior to starting the investigation*

☐ Updates on safety and adverse effects reported to the sponsor about the drug

☐ Written IND Safety Reports of AEs related to the drug that is both serious and unexpected or findings in laboratory animals that suggests a significant risk for humans
   *(Notification should be made within 15 calendar days after receipt of information. For any unexpected fatal or life-threatening experience associated with the use of the drug notification should be made within 7 calendar days after receipt of information)*

☐ Notification (of FDA, all participating investigators, and institutional review boards) if the drug presents unreasonable and significant risk to subjects and discontinue investigation within 5 working days

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5. Ensuring control and representation of the investigational new drug

☐ Ship IND only to investigators participating in the investigation

☐ Maintain adequate records showing receipt, shipment, or other disposition of IND (Records must include name of investigator to whom drug is shipped, date, quantity, and batch or code mark of each shipment)

☐ Ensure the return of all unused supplies/IND from each investigator and maintain adequate records of all returns/disposal of IND

☐ Compliance with the Controlled Substances Act

☐ Ensure the immediate packaging of the IND intended for human use bears a label with the statement, Caution: New Drug-Limited by Federal (or United States) law to investigational use, and the drug label does not bear any statement that is false or misleading and does not represent that the IND is safe or effective for the purposes for which it is under investigation

☐ Must not represent the IND in a promotional context that it is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.

☐ Current Good Manufacturing Practices (cGMPs): Ensure the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals in compliance with the requirements of §501(a)(2)(B) of the FD&C Act

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IRB documents (as applicable):

☐ Correspondence
☐ Approval letters for initial approval, CRs, amendments

Other Requirements:

☐ Sponsor SOPs?
☐ Maintaining all regulatory documentation including original IND application, FDA forms 1571, FDA letter of no objection, IND safety reports, amendments, annual reports, and any other correspondence with the FDA, participating site investigators, and CRO (if applicable)
☐ SIV documentation
☐ Allowing the FDA, at reasonable times, to and copy and verify any records or reports relating to the clinical investigation
☐ Documentation of correspondence with study investigators
☐ ICFs
☐ DSMB, as applicable
☐ Sample CRFs, as applicable
☐ CTD, as applicable
☐ Notification of Trial Termination

☐ If trial is closed, study information is appropriately stored
  o Location: _________________________________
  o Address: ______________________________________
    ______________________________________
    ______________________________________
  o Responsible person: ________________________
  o Phone#: _________________________________

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