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  - ❒ If the drug has been withdrawn from investigation or marketing in any other country for reasons r/t safety and/or effectiveness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

Comments:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

(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:*

	Annual Report #: _____ Date: _____	Annual Report #: _____ Date: _____	Annual Report #: _____ Date: _____	Annual Report #: _____ Date: _____
Study title, purpose, patient population, and whether study has been completed				
Summary of study progress in the past year				
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				
If study has been completed or interim results are available, these should be provided				
Narrative or tabular summary of most frequent and most serious AEs by body system				
Summary of all IND safety reports submitted in the past year				
List of subject deaths to include cause of death				
List of subjects who dropped out d/t AEs				
Any information learned about the drug, dosing, bioavailability, etc.				
List of preclinical studies completed or in progress				
As applicable, any manufacturing or microbiological changes made during past year				
Investigational plan for upcoming year				
As applicable, description of updates to IB				
For Phase 1 studies, description of protocol changes in previous year that were not previously reported to FDA via amendment				
Summary information of foreign marketing, including approval, withdrawal, or suspension				

(c) Amendments (note FDA Form 3674 as applicable)

Amendment #	**Type:**
______ ______ ______ ______ ______ ______	❐ Initial IND ❐Response to Clinical Hold ❐ Response to FDA Request for Info ❐ Reactivation ❐Annual Report ❐General Correspondence ❐Development Safety Update (DSUR) ❐Other: ______________________________ **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
______ ______ ______ ______ ______ ______	❐ Initial IND ❐Response to Clinical Hold ❐ Response to FDA Request for Info ❐ Reactivation ❐Annual Report ❐General Correspondence ❐Development Safety Update (DSUR) ❐Other: ______________________________ **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
______ ______ ______ ______ ______ ______	❐ Initial IND ❐Response to Clinical Hold ❐ Response to FDA Request for Info ❐ Reactivation ❐Annual Report ❐General Correspondence ❐Development Safety Update (DSUR) ❐Other: ______________________________ **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
______ ______ ______ ______ ______ ______	❐ Initial IND ❐Response to Clinical Hold ❐ Response to FDA Request for Info ❐ Reactivation ❐Annual Report ❐General Correspondence ❐Development Safety Update (DSUR) ❐Other: ______________________________ **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

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:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

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:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

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

Comments:

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

Comments:

Checklist for Sponsor Responsibilities

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#: _____

Comments:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____