Checklist for Sponsor Responsibilities

1. Maintaining an effective IDE with respect to the investigations

- ❒ (a) Initial IDE submission present (and contains the following):
  - ❒ Name, address, phone # of the Sponsor
  - ❒ Date of application: _____
  - ❒ Name of investigational device: _____
  - ❒ Report of prior investigations with device (includes bibliography of publications, summary of unpublished information, and statement that GLP was followed for pre-clinical or reason why not followed
  - ❒ Methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate, installation of the device
  - ❒ Sample investigator agreement (akin to 1572)
  - ❒ List of investigators
  - ❒ Signed investigator agreements (akin to 1572s)
  - ❒ Name, address, and chairperson of each IRB
  - ❒ Name, address, and chairperson of each participating institution
  - ❒ Cost of device, if being sold
  - ❒ A claim for categorical exclusion under 25.30 or 25.34 or an environmental assessment under 25.40
  - ❒ Copies of all device labeling
  - ❒ ICFs and copies of all forms/materials being presented to subjects

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(b) Investigation Plan must include:

- ❒ (a) **Purpose.** The name and intended use of the device and the objectives and duration of the investigation.
- ❒ (b) **Protocol.** A written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound.
- ❒ (c) **Risk analysis.** A description and analysis of all increased risks to which subjects will be exposed by the investigation; the manner in which these risks will be minimized; a justification for the investigation; and a description of the patient population, including the number, age, sex, and condition.
- ❒ (d) **Description of device.** A description of each important component, ingredient, property, and principle of operation of the device and of each anticipated change in the device during the course of the investigation.
- ❒ (e) **Monitoring procedures.** The sponsor's written procedures for monitoring the investigation and the name and address of any monitor.
- ❒ (f) **Labeling.** Copies of all labeling for the device.
- ❒ (g) **Consent materials.** Copies of all forms and informational materials to be provided to subjects to obtain informed consent.
- ❒ (h) **IRB information.** A list of the names, locations, and chairpersons of all IRB's that have been or will be asked to review the investigation, and a certification of any action taken by any of those IRB's with respect to the investigation.
- ❒ (i) **Other institutions.** The name and address of each institution at which a part of the investigation may be conducted that has not been identified in paragraph (h) of this section.
- ❒ (j) **Additional records and reports.** A description of records and reports that will be maintained on the investigation in addition to those prescribed in subpart G.

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(c). 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 safety reports / UADEs 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 device				
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				
Summary information of foreign marketing, including approval, withdrawal, or suspension				

(d) Supplements (note FDA Form 3674 as applicable)

Supplement #	**Type:**
____________ ____________ ____________ ____________ ____________ ____________	❒ Initial IDE ❒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 ❒New IRB **Request for** ❒ Meeting ❒Proprietary Name Review ❒ Special Prot. Assessment ❒Formal Dispute **IDE Safety Report** ❒Initial Written Report ❒Follow-up to Written Report
____________ ____________ ____________ ____________ ____________ ____________	❒ Initial IDE ❒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 ❒New IRB **Request for** ❒ Meeting ❒Proprietary Name Review ❒ Special Prot. Assessment ❒Formal Dispute **IDE Safety Report** ❒Initial Written Report ❒Follow-up to Written Report
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2. Selection of qualified investigators

Comments:

The following are present for each site investigator:

- ❒ Signed Form Investigator Agreement (akin to FDA 1572)
- ❒ 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

3. Ensuring proper monitoring of investigations

Comments:

- ❒ Select a monitor qualified by training and experience to monitor the progress of all investigations conducted under its IND
- ❒ Have a written, adequate monitoring plan, including the review and evaluation of the data and device safety and effectiveness
- ❒ UADEs
- ❒ Monitoring reports

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 device
- ❒ UADEs
- ❒ Written Safety Reports of AEs related to the device 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 device presents unreasonable and significant risk to subjects and discontinue investigation within 5 working days

Comments:

4. Ensuring control and representation of the device

- ❒ Ship device only to investigators participating in the investigation
- ❒ Maintain adequate records showing receipt, shipment, or other disposition of IDE (*Records must include name of investigator to whom device is shipped, date, quantity, and batch or code mark of each shipment)*
- ❒ Ensure the return of all unused supplies from each investigator and maintain adequate records of all returns/disposal of IDE
- ❒ Compliance with the Controlled Substances Act
- ❒ Ensure the immediate packaging of the IDE intended for human use bears a label with the statement, ***"CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use."***, and the device 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 IDE in a promotional context that it is safe or effective for the purposes for which it is under investigation or otherwise promote the device.
- ❒ Current Good Manufacturing Practices (cGMPs): Ensure the minimum current good manufacturing practice for preparation of device 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 IDE application, FDA letter of no objection, IDE 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: _____
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  - o Responsible person: _____
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