Dartmouth
CLINICAL TRIALS OFFICE

FDA Sponsor and Investigator Responsibility Checklist

Principal Investigator:

Study Name:

CPHS #:

IND/IDE #:

Name of IND/IDE holder:

The following checklist is created based on the Sponsor and Investigator responsibilities outlined in the FDA Code of Federal Regulations. Onsite documents (listed in the right column) correspond to the regulations written in 21 CFR 312 (drugs, biologics) and 812 (devices).

FDA Regulations CFR 312 / 812	**Corresponding Onsite Documents**
1.0 Regulatory Documentation	
1.1 As the Sponsor, maintain an effective IND/IDE ▪ Protocol amendments o New protocol o Changes to existing protocol o New Investigator ▪ Information Amendments o New technical information o Discontinuation of clinical investigation ▪ IND/IDE safety reports o Written reports (e.g., MedWatch 3500A) to FDA and all participating investigators within required timeframe o Follow-up information to a safety report should be submitted as soon as available ▪ Annual reports o Within 60 days of the anniversary date that the IND/IDE went into effect	All correspondence with FDA including: ☐ Original IND/IDE application (including 1571) ☐ FDA letter of no objection ☐ Amendments (w/ 1571) ☐ IND/IDE Safety reports (w/ 1571) ☐ Evidence of correspondence to other investigators ☐ N/A ☐ Annual reports (w/ 1571) ☐ Correspondence with FDA ☐ Other: _____
1.2 As the Investigator, assure IRB review and approval	IRB documentation ☐ Initial review ☐ Continuing review ☐ Amendments ☐ Serious Adverse Event reports ☐ Protocol deviations ☐ Eligibility Exception Request ☐ Current IB/Device Manual ☐ Other IRB correspondence
2.0 Qualified Investigators	
2.1 As the Sponsor, selecting qualified investigators a. Select PIs qualified by training and experience b. Investigational product will be shipped to only those investigators participating in the study c. Obtain information from selected PIs d. Maintain complete and accurate records involving Investigators' financial disclosure (a and b apply only if multicenter trial)	For **each** site Investigator; or ☐ Not applicable ☐ Signed FDA form 1572 /Investigator Agreement (IA) ☐ CV(s) (all names listed on 1572 or IA) ☐ Financial disclosure for PI and those listed on 1572/IA; written memo disclosing any financial conflicts/interest ☐ Clinical protocol

2.2 As Investigator, conduct study according to signed investigator statement, protocol, and applicable regulations; ▪ Report violations/deviations to IRB; ▪ Protect rights, safety and welfare of subjects; ▪ Promptly report to IRB any "on-site" adverse events in accordance with institutional requirements; ▪ Obtain informed consent in accordance with provisions in 21 CFR 50	*Review guidelines applicable to study*: ☐ Protocol deviations ☐ Adverse event reporting requirements ☐ CPHS ☐ FDA ☐ Unexpected Problems Involving Risk to Subjects or Others
3.0 Monitoring	
3.1 As the Sponsor, ensure ongoing monitoring investigations a. Select monitors by training and experience b. Ensure proper monitoring c. Ensure PI compliance or discontinue shipments of the investigational drug/device d. Review and evaluate drug/device safety and effectiveness e. Discontinue investigation within 5 working days when unreasonable and significant risk to subject are identified	☐ Documentation of safety monitoring plan ☐ Documentation of data monitoring plan Monitor of study: ☐ PI ☐ Other: _____ ☐ All Correspondence with monitor; ☐ N/A ☐ Monitoring log Who will be reviewing safety data: ☐ PI ☐ DSMB ☐ Medical Monitor ☐ Other _____
4.0 Record Keeping	
4.1 As the Investigator, maintain adequate and accurate case histories on each subject's participation in the trial	☐ Source data ☐ Progress notes ☐ Concomitant medications recorded ☐ Subject eligibility documented ☐ CRFs ☐ Appropriately documented consent forms ☐ Documentation that informed consent was obtained prior to study procedures ☐ Documentation that subject was given a copy of signed and dated consent form ☐ Signature/date of staff obtaining data
5.0 Drug/Device	
5.1 As the Investigator, ensure control of investigational drug/device ▪ Drug/device will be administered only to those subjects enrolled in the clinical study and under investigator or designee's supervision	☐ Enrollment log/ Randomization log ☐ Delegation of Responsibility log

5.2 As the Investigator, record of drug/device disposition a. Maintain adequate record of receipt and shipment of investigational drug/device b. Assure return of all unused investigational drug/device from individual investigators participating in trial or authorize alternative disposition of unused product c. Maintain written records of any disposition of the drug/device	Drug/device Receipt ☐ Drug/device received from Industry Drug/device accountability log includes: ☐ Receipt date ☐ Quantity ☐ Lot # ☐ Return/disposition ☐ Method of disposal ☐ Drug/device manufactured onsite Drug/device Shipment ☐ Single center study – no drug/device shipment ☐ Drug/device shipped to multiple sites Drug/device accountability log includes: ☐ Date ☐ Destination ☐ Who shipped ☐ Quantity ☐ Lot # ☐ Return/disposition ☐ Method of disposal Drug/device dispensing record including: ☐ Research Pharmacy will manage drug ☐ Date ☐ Lot #/ device # ☐ Quantity ☐ ID of subject administered/implanted ☐ Disposition/record of return ☐ ID of person dispensing ☐ Return of drug/device, count & reason
5.3 As the Sponsor, will inform other investigators about the investigational product (if applicable). All Sponsors will keep each investigator informed of new observations discovered by or reported to the sponsor on the investigational product.	☐ Current Investigator's Brochure/Device Manual ☐ Single study center ☐ Multi-center study ☐ Plan to distribute updated information to site Investigators about product, safety information, etc

6.0 Inspection	
6.1 As the Sponsor or Investigator: Inspection of Investigators records and reports	Upon request, permit FDA officer to access, copy and verify any records or reports made by the investigator ☐ Basic review of FDA inspection procedures
7.0 Communication with Sponsor or Investigator, if applicable	
7.1 Transfer of obligations from the IND/IDE holder	☐ Written documentation on site describing transfer of responsibility ☐ N/A
7.2 Investigator Reports a. Progress reports b. Safety reports c. Final reports d. Financial disclosure reports	☐ All pertinent correspondence between sponsor and investigator (enrollment numbers, adverse events, financial information and any changes in financial information) ☐ N/A
7.3 Correspondence with sponsor, monitor, and FDA (if applicable)	☐ Sponsor (if applicable) ☐ Monitor (if applicable) ☐ FDA (if applicable)
8.0 Additional GCP documentation	
8.1 Laboratory Documentation	☐ Current laboratory certification ☐ Laboratory normal values
8.2 Documentation of study staff signature/initials	☐ Staff signature log