	CHECKLIST: Investigator Self-Assessment		
	NUMBER	**DATE**	**PAGE**
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Human Research (Non-Clinical Trials)

Principal Investigator	
Protocol #/Study Title	/
Name of Person Completing Checklist	
Date Completed	

The purpose of this checklist is to allow investigators to conduct a quality improvement self-assessment and/or for QA/QI staff to conduct quality improvement assessments of investigators. This section is designed for research studies that are NOT considered clinical trials. Please complete this section if the research study you are conducting is considered Social, Behavioral or Education research. For Clinical Trials, please begin on page 3.

1. Regulatory Documentation for Each Study	
☐ **Yes** ☐ **No** ☐ **N/A**	Grant
☐ **Yes** ☐ **No** ☐ **N/A**	Sponsor's Agreement, Contract
☐ **Yes** ☐ **No** ☐ **N/A**	Annual progress reports for grant **Total Number:**
☐ **Yes** ☐ **No** ☐ **N/A**	Most recent version of the IRB approved protocol
☐ **Yes** ☐ **No** ☐ **N/A**	Previous versions of the IRB approved protocol **Total Number:**
☐ **Yes** ☐ **No** ☐ **N/A**	Most recent version of the IRB approved recruitment materials
☐ **Yes** ☐ **No** ☐ **N/A**	Previous versions of the IRB approved recruitment materials **Total Number:**
☐ **Yes** ☐ **No** ☐ **N/A**	Most recent version of the IRB approved consent document(s)
☐ **Yes** ☐ **No** ☐ **N/A**	Previous versions of the IRB approved consent document(s) **Total Number:**
☐ **Yes** ☐ **No** ☐ **N/A**	Most recent version of the IRB approved parental permission/assent document(s)
☐ **Yes** ☐ **No** ☐ **N/A**	Previous versions of the IRB approved parental permission/assent document(s) **Total Number:**
☐ **Yes** ☐ **No** ☐ **N/A**	Most recent version of the IRB approved study tools, e.g., survey/questionnaire
☐ **Yes** ☐ **No** ☐ **N/A**	Previous versions of the IRB approved study tools, e.g., survey/questionnaire **Total Number:**
☐ **Yes** ☐ **No** ☐ **N/A**	Correspondence with the IRB on file: (look for signature and date when needed for submission)
☐ **Yes** ☐ **No** ☐ **N/A**	Initial IRB application
☐ **Yes** ☐ **No** ☐ **N/A**	Continuing review(s). **Total Number:**
☐ **Yes** ☐ **No** ☐ **N/A**	Modification Request(s). **Total Number:**
☐ **Yes** ☐ **No** ☐ **N/A**	Reportable New Information form(s). **Total Number:**
☐ **Yes** ☐ **No** ☐ **N/A**	Notifications of IRB disapproval, deferral, modifications required to secure approval
☐ **Yes** ☐ **No** ☐ **N/A**	Responses to IRB actions
☐ **Yes** ☐ **No** ☐ **N/A**	IRB suspensions or terminations
☐ **Yes** ☐ **No** ☐ **N/A**	Copies of email correspondence with the IRB
☐ **Yes** ☐ **No** ☐ **N/A**	Other communications with the IRB
☐ **Yes** ☐ **No** ☐ **N/A**	Records of investigator and study staff human research training
☐ **Yes** ☐ **No** ☐ **N/A**	Training certificates are valid (completed within the past 3 years or other applicable period, per institutional policy)
☐ **Yes** ☐ **No** ☐ **N/A**	CVs or other relevant documents (biosketch/resume) evidencing qualifications of PI, co-investigators, and all study personnel
☐ **Yes** ☐ **No** ☐ **N/A**	CVs/other relevant information have been updated within the past two years or other applicable period, per

	institutional policy)
☐ **Yes** ☐ **No** ☐ **N/A**	CVs/other relevant information are signed and dated
☐ **Yes** ☐ **No** ☐ **N/A**	Signed agreements/contracts between parties (e.g., MOA, DUA, LDT)
☐ **Yes** ☐ **No** ☐ **N/A**	Correspondences to and from the funding agency
☐ **Yes** ☐ **No** ☐ **N/A**	IRB roster
☐ **Yes** ☐ **No** ☐ **N/A**	Documentation of IRB's Federalwide Assurance (FWA) Number
2. Document Retention	
☐ **Yes** ☐ **No** ☐ **N/A**	Regulatory documentation (e.g., contents of the Regulatory Binder) are retained for at least XXXXX years after closing out the Human Research
☐ **Yes** ☐ **No** ☐ **N/A**	Records for sponsored research are retained until the sponsor authorized destruction of the records. Instructions or date of authorized destruction:
3. Subject Recruitment Procedures	
☐ **Yes** ☐ **No** ☐ **N/A**	Are the IRB-approved recruitment methods being followed?
☐ **Yes** ☐ **No** ☐ **N/A**	Have all recruitment materials (e.g., advertisements and telephone scripts) been approved by the IRB? Note: ALL recruitment materials must be approved prior to use and must be re-approved at the time of continuing review.
4. Data and Safety Monitoring	
☐ **Yes** ☐ **No** ☐ **N/A**	Is there a Data Safety Monitoring Plan (DSMP) for this study?
☐ **Yes** ☐ **No** ☐ **N/A**	Has the DSMP been followed per the IRB approved protocol?
☐ **Yes** ☐ **No** ☐ **N/A**	Is there a Data and Safety Monitoring Board (DSMB) for this study?
☐ **Yes** ☐ **No** ☐ **N/A**	Have all DSMB reports been submitted to the IRB? **Total Number:**

Clinical Trials

Principal Investigator	
Protocol #/Study Title	/
Name of Person Completing Checklist	
Date Completed	

The purpose of this checklist is to allow investigators to conduct a quality improvement self-assessment and/or for QA/QI staff to conduct quality improvement assessments of investigators. This section is designed for Clinical Trials.[1] The reviewer should identify and complete the applicable sections for each unique study.

1. Regulatory Documentation[2]

☐ Yes ☐ No ☐ N/A	Grant
☐ Yes ☐ No ☐ N/A	Sponsor's Agreement, Contract
☐ Yes ☐ No ☐ N/A	Annual progress reports for grant **Total Number:**
☐ Yes ☐ No ☐ N/A	Most recent version of the IRB approved protocol
☐ Yes ☐ No ☐ N/A	Previous versions of the IRB approved protocol **Total Number:**
☐ Yes ☐ No ☐ N/A	Most recent version of the IRB approved recruitment materials
☐ Yes ☐ No ☐ N/A	Previous versions of the IRB approved recruitment materials **Total Number:**
☐ Yes ☐ No ☐ N/A	Most recent version of the IRB approved consent document(s)
☐ Yes ☐ No ☐ N/A	Previous versions of the IRB approved consent document(s) **Total Number:**
☐ Yes ☐ No ☐ N/A	Most recent version of the IRB approved parental permission/assent document(s)
☐ Yes ☐ No ☐ N/A	Previous versions of the IRB approved parental permission/assent document(s) **Total Number:**
☐ Yes ☐ No ☐ N/A	Most recent version of IRB approved information, e.g., brochure, information sheet, results letter, etc.
☐ Yes ☐ No ☐ N/A	Previous versions of IRB approved information, e.g., brochure, information sheet, results letter, etc. **Total Number:**
☐ Yes ☐ No ☐ N/A	Most recent version of the IRB approved study tools, e.g., survey/questionnaire
☐ Yes ☐ No ☐ N/A	Previous versions of the IRB approved study tools, e.g., survey/questionnaire **Total Number:**
☐ Yes ☐ No ☐ N/A	Correspondence with the IRB on file: (look for signature and date when needed for submission)
☐ Yes ☐ No ☐ N/A	Initial IRB application
☐ Yes ☐ No ☐ N/A	Continuing review(s). **Total Number:**
☐ Yes ☐ No ☐ N/A	Modification Request(s). **Total Number:**
☐ Yes ☐ No ☐ N/A	Reportable New Information form(s).

[1] FDA defines Clinical Investigation as, "*Clinical investigation* means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies." (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3). NIH defines Clinical Trial as, "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html)

[2] Copies of correspondences my be retained in hardcopy or electronic format (e.g., shared folder space)

	Total Number:
☐ **Yes** ☐ **No** ☐ **N/A**	Notifications of IRB disapproval, deferral, modifications required to secure approval
☐ **Yes** ☐ **No** ☐ **N/A**	Responses to IRB actions
☐ **Yes** ☐ **No** ☐ **N/A**	IRB suspensions or terminations
☐ **Yes** ☐ **No** ☐ **N/A**	Copies of email correspondence with the IRB
☐ **Yes** ☐ **No** ☐ **N/A**	Other communications with the IRB
☐ **Yes** ☐ **No** ☐ **N/A**	Records of investigator and study staff human research training
☐ **Yes** ☐ **No** ☐ **N/A**	Training certificates are valid (completed within the past 3 years or appropriate amount of time per institutional policy)
☐ **Yes** ☐ **No** ☐ **N/A**	CVs or other relevant documents (biosketch/resume) evidencing qualifications of PI, co-investigators, and all study personnel
☐ **Yes** ☐ **No** ☐ **N/A**	CVs/other relevant information have been updated within the past two years (or appropriate amount of time per institutional policy or appropriate amount of time per institutional policy)
☐ **Yes** ☐ **No** ☐ **N/A**	CVs/other relevant information are signed and dated
☐ **Yes** ☐ **No** ☐ **N/A**	Signed agreements/contracts between parties
☐ **Yes** ☐ **No** ☐ **N/A**	Correspondences to and from the funding agency or sponsor
☐ **Yes** ☐ **No** ☐ **N/A**	IRB roster
☐ **Yes** ☐ **No** ☐ **N/A**	Documentation of Federalwide Assurance (FWA) Number
2. Logs	
☐ **Yes** ☐ **No** ☐ **N/A**	Participant screening log. **Number screened:**
☐ **Yes** ☐ **No** ☐ **N/A**	Participant identification code list
☐ **Yes** ☐ **No** ☐ **N/A**	Participant enrollment log. **Number enrolled:**
☐ **Yes** ☐ **No** ☐ **N/A**	Study Staff Signature and Delegation of Responsibility log
☐ **Yes** ☐ **No** ☐ **N/A**	Signature log reflects all current staff working on the study
☐ **Yes** ☐ **No** ☐ **N/A**	Signature log reflects all previous staff working on the study
☐ **Yes** ☐ **No** ☐ **N/A**	Staff working on the study are IRB approved
☐ **Yes** ☐ **No** ☐ **N/A**	Signature log reflects PI's signature
☐ **Yes** ☐ **No** ☐ **N/A**	Monitoring/auditing log. **Monitoring frequency:**
☐ **Yes** ☐ **No** ☐ **N/A**	Monitoring/auditing log includes a description of monitoring activities
☐ **Yes** ☐ **No** ☐ **N/A**	Record of retained body fluids/ tissue samples
☐ **Yes** ☐ **No** ☐ **N/A**	Correspondences to and from the sponsor/CRO
☐ **Yes** ☐ **No** ☐ **N/A**	Letters
☐ **Yes** ☐ **No** ☐ **N/A**	Meeting notes
☐ **Yes** ☐ **No** ☐ **N/A**	Notes of telephone calls
☐ **Yes** ☐ **No** ☐ **N/A**	Instructions for handling of investigational product(s) and trial-related materials (if not in protocol or investigator's brochure)
☐ **Yes** ☐ **No** ☐ **N/A**	Decoding procedures for blinded trials
☐ **Yes** ☐ **No** ☐ **N/A**	Normal lab values
☐ **Yes** ☐ **No** ☐ **N/A**	Updates to normal lab values
☐ **Yes** ☐ **No** ☐ **N/A**	Lab certification (e.g. CAP, CLIA)
☐ **Yes** ☐ **No** ☐ **N/A**	Updates to lab certification (e.g. CAP, CLIA)
☐ **Yes** ☐ **No** ☐ **N/A**	Lab director's CV
☐ **Yes** ☐ **No** ☐ **N/A**	Updates to lab director's CV
☐ **Yes** ☐ **No** ☐ **N/A**	Site Initiation report/visit documentation
☐ **Yes** ☐ **No** ☐ **N/A**	Study close-out report/visit documentation
☐ **Yes** ☐ **No** ☐ **N/A**	Is there a Data Safety Monitoring Plan (DSMP) for this study?
☐ **Yes** ☐ **No** ☐ **N/A**	Has the DSMP been followed per the IRB approved protocol?
☐ **Yes** ☐ **No** ☐ **N/A**	Is there a DSMB for this study?
☐ **Yes** ☐ **No** ☐ **N/A**	DSMB reports, meeting minutes or indication of DSMB review/recommendations. **DSMB frequency:**
☐ **Yes** ☐ **No** ☐ **N/A**	Most recently approved sample case report forms (CRF)/Data Collection Sheets

☐ Yes ☐ No ☐ N/A	For marketed products, a package insert/product information
3. Document Retention	
☐ Yes ☐ No ☐ N/A	Regulatory documentation (e.g., contents of the Regulatory Binder) are retained for at least XXXXX years after closing out the Human Research
☐ Yes ☐ No ☐ N/A	Records for sponsored research are retained until the sponsor authorized destruction of the records. Instructions or date of authorized destruction:
4. FDA Investigational New Drug Study-specific Records [3]	
☐ Yes ☐ No	Is the PI a sponsor-investigator[4] (IND holder)? Fill out section 11
☐ Yes ☐ No ☐ N/A	Is there a signed FDA Form 3674 – Certificate of Registration to ClicincalTrials.gov on file? A FDA Form 3674 should be on file for each applicable study.
☐ Yes ☐ No ☐ N/A	Is a signed Investigator Statement (Form FDA 1572) on file for each investigator involved in the study?
☐ Yes ☐ No ☐ N/A	Is documentation verifying the IND number on file (eg copy of IB with IND number, IND acknowledgment letter from FDA for indication under study)?
	If the answer to the above question is yes, and the PI is a sponsor-investigator, please complete section 11 below . If the answer to the above question is no, please do not complete Section 11.
☐ Yes ☐ No ☐ N/A	A signed current FDA 1572 for all clinical sites?
☐ Yes ☐ No ☐ N/A	Is there a monitor[5] for this study?
☐ Yes ☐ No ☐ N/A	Are copies of all previously conducted monitoring reports received on file?
☐ Yes ☐ No ☐ N/A	Is there a monitoring log on file for all monitoring previously conducted?
☐ Yes ☐ No ☐ N/A	Previous signed versions of FDA 1572 **Total Number:**
☐ Yes ☐ No ☐ N/A	A current signed financial disclosure form (Form 3454 or 3455) submitted to the sponsor from each investigator listed on the 1572 or in the Investigator Statement
☐ Yes ☐ No ☐ N/A	Has the IRB been notified for all of the research team members listed on the FDA Form 1572 or who signed an Investigator Agreement?
☐ Yes ☐ No ☐ N/A	Valid licensure for each investigator/staff member listed on the 1572
☐ Yes ☐ No ☐ N/A	Current investigator brochure or product label
☐ Yes ☐ No ☐ N/A	Previous versions of or updates to the investigator brochure
☐ Yes ☐ No ☐ N/A	There is shipping log for each drug, which captures the following:
☐ Yes ☐ No ☐ N/A	Date shipment received
☐ Yes ☐ No ☐ N/A	Shipment # from packing slip study drug
☐ Yes ☐ No ☐ N/A	Batch#/lot #/code mark
☐ Yes ☐ No ☐ N/A	Expiration date
☐ Yes ☐ No ☐ N/A	# of boxes, kits, or drugs per lot #
☐ Yes ☐ No ☐ N/A	# of bottles, vials, inhalers, or drugs per box or kit
☐ Yes ☐ No ☐ N/A	Condition of study drug shipment (Intact/damaged)
☐ Yes ☐ No ☐ N/A	Receiver's name
☐ Yes ☐ No ☐ N/A	There is an accountability log for each drug under investigation, which captures the following:
☐ Yes ☐ No ☐ N/A	Participant ID #, initials, or name
☐ Yes ☐ No ☐ N/A	Lot or kit number
☐ Yes ☐ No ☐ N/A	# Bottles, vials, etc.
☐ Yes ☐ No ☐ N/A	Amount of study drug per bottle, vial, etc.
☐ Yes ☐ No ☐ N/A	Total amount dispensed
☐ Yes ☐ No ☐ N/A	Initials
☐ Yes ☐ No ☐ N/A	Date dispensed
☐ Yes ☐ No ☐ N/A	# Of bottles, vials, etc. Returned

[3] The Investigational New Drug (IND) application is the process through which a drug sponsor alerts the FDA of its intentions to conduct clinical studies with an investigational drug. Refer to FDA guidance about when an IND is required.

[4] Sponsor-investigator is the individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A Sponsor-investigator is required to fulfill the responsibilities of both the Investigator and the Sponsor.

[5] An individual who reviews the subject safety and protocol adherence, as stated in the protocol data and safety monitoring plan. For IND studies this is the individual listed as the *monitor* in section 14 of the FDA Form 1571.

☐ Yes ☐ No ☐ N/A	Total amount returned
☐ Yes ☐ No ☐ N/A	Balance: number dispensed less number returned
☐ Yes ☐ No ☐ N/A	Comments: participant lost, discarded, etc.
☐ Yes ☐ No ☐ N/A	Person who dispensed the drug
☐ Yes ☐ No ☐ N/A	The investigator furnishes all reports to/from the sponsor of the drug
☐ Yes ☐ No ☐ N/A	An investigator shall promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator shall report the adverse effect immediately to the sponsor and IRB

5. Study Records (IDE studies)[6]	
☐ Yes ☐ No ☐ N/A	Is a signed Investigator Statement on file for each investigator involved in the study?
☐ Yes ☐ No ☐ N/A	Is documentation verifying the IDE number on file (e.g. copy of device manual with IDE number, IDE acknowledgment letter from FDA for indication under study)??
☐ Yes ☐ No ☐ N/A	Is a copy of the original IDE application to the FDA on file?
☐ Yes ☐ No ☐ N/A	Are ALL amendments to the IDE on file?
☐ Yes ☐ No ☐ N/A	Are ALL annual reports to the IDE on file?
☐ Yes ☐ No ☐ N/A	Are ALL safety reports to the IDE on file?
☐ Yes ☐ No ☐ N/A	Is ALL correspondence to the FDA on file?
☐ Yes ☐ No ☐ N/A	Is there a monitor[7] for this study?
☐ Yes ☐ No ☐ N/A	Are copies of all monitoring reports received on file?
☐ Yes ☐ No ☐ N/A	Is there a monitoring log on file?
☐ Yes ☐ No ☐ N/A	Previous versions of signed Investigator Statements **Total Number:**
☐ Yes ☐ No ☐ N/A	A current signed financial disclosure form submitted to the sponsor from each investigator listed in the Signed Investigator Agreement
☐ Yes ☐ No ☐ N/A	Previous versions of signed financial disclosure forms submitted to the sponsor from each investigator in the Investigator Statement
☐ Yes ☐ No ☐ N/A	Has the IRB been notified for all of the research team members listed who signed an Investigator Agreement?
☐ Yes ☐ No ☐ N/A	Valid licensure for each investigator/staff member listed on the Investigator Statement
☐ Yes ☐ No ☐ N/A	Current device manual
☐ Yes ☐ No ☐ N/A	Previous versions of or updates to the device manual **Total Number:**
☐ Yes ☐ No ☐ N/A	There is shipping log for each device, which captures the following
☐ Yes ☐ No ☐ N/A	Date shipment received
☐ Yes ☐ No ☐ N/A	Shipment # from packing slip study device
☐ Yes ☐ No ☐ N/A	Expiration date
☐ Yes ☐ No ☐ N/A	# of boxes, kits, or devices per lot #
☐ Yes ☐ No ☐ N/A	# of bottles or devices per box or kit
☐ Yes ☐ No ☐ N/A	Condition of study drug/device shipment (Intact/damaged)
☐ Yes ☐ No ☐ N/A	Receiver's name
☐ Yes ☐ No ☐ N/A	There is an accountability log for each device under investigation, which captures the following:
☐ Yes ☐ No ☐ N/A	Participant ID#, initials, or name
☐ Yes ☐ No ☐ N/A	Model or serial #
☐ Yes ☐ No ☐ N/A	Date used/implemented
☐ Yes ☐ No ☐ N/A	Device disposition
☐ Yes ☐ No ☐ N/A	Comments, such as malfunctions, device failure, disposition of unused devices (returned to sponsor/destroyed,) or any other pertinent information concerning the device
☐ Yes ☐ No ☐ N/A	Person who administered the device
☐ Yes ☐ No ☐ N/A	Correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required report

[6] Investigational Device Exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Pre-market approval (PMA) or Pre-market Notification 510(k) submission to FDA.

[7] An individual who reviews the subject safety and protocol adherence, as stated in the protocol data and safety monitoring plan. For IDE studies this individual is identified in the investigational plan.

☐ Yes ☐ No ☐ N/A	Reports of unanticipated adverse device effects.
☐ Yes ☐ No ☐ N/A	Reports of withdrawal of IRB approval.
☐ Yes ☐ No ☐ N/A	Progress reports submitted to the sponsor, the monitor, and the reviewing IRB at regular intervals **Total Number:**
☐ Yes ☐ No ☐ N/A	Reports of deviations from the investigational plan.
☐ Yes ☐ No ☐ N/A	Reports of emergency use of the investigational device without informed consent.
☐ Yes ☐ No ☐ N/A	Final report.
6. Document Retention (IRB Policy)	
☐ Yes ☐ No ☐ N/A	Regulatory documentation (e.g., contents of the Regulatory Binder) are retained for at least XXXX years after closing out the Human Research. If the Human Research is sponsored, contact the sponsor before disposing of Human Research records as there may be specific policies related to record retention Date of Document Destruction (if known):
7. Document Retention (IND studies)	
☐ Yes ☐ No ☐ N/A	An investigator retains records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified Date of Planned Document Destruction (if known):
8. Document Retention (IDE studies)	
☐ Yes ☐ No ☐ N/A	An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol Date of Document Destruction (if known):
9. Investigator Study Conduct Responsibilities (IND studies)	
☐ Yes ☐ No ☐ N/A	Investigators are responsible for the control of drugs under investigation
☐ Yes ☐ No ☐ N/A	Investigators administer the drug only to participants under their personal supervision or under the supervision of a sub-investigator responsible to the investigator
☐ Yes ☐ No ☐ N/A	Investigators does not supply the investigational drug to any person not authorized to receive it
☐ Yes ☐ No ☐ N/A	If the investigation is terminated, suspended, discontinued, or completed, investigators returns the unused supplies of the drug to the sponsor, or otherwise provides for disposition of the unused supplies of the drug as authorized by the sponsor
☐ Yes ☐ No ☐ N/A	If an investigational drug is participant to the Controlled Substances Act, investigators take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution
10. Investigator Study Conduct Responsibilities (IDE studies)	
☐ Yes ☐ No ☐ N/A	Investigators permit an investigational device to be used only with participants under the investigator's supervision
☐ Yes ☐ No ☐ N/A	Investigators do not supply an investigational device to any person not authorized to receive it
☐ Yes ☐ No ☐ N/A	Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, investigators return to the sponsor any unused device or otherwise dispose of the device as the sponsor directs
☐ Yes ☐ No ☐ N/A	If the investigation is terminated, suspended, discontinued, or completed, investigators returns the unused supplies of the drug to the sponsor, or otherwise provides for disposition of the unused supplies of the drug as authorized by the sponsor
	Investigators prepare and submit the following reports to the sponsor:
☐ Yes ☐ No ☐ N/A	Any unanticipated adverse device effect occurring during an investigation. (As soon as possible, but in no event later than 10 working days after first learning of the effect unless required sooner by sponsor.)
☐ Yes ☐ No ☐ N/A	Withdrawal of approval by the reviewing IRB of the investigator's part of an investigation. (Within 5 working days unless required sooner by sponsor)
☐ Yes ☐ No ☐ N/A	Progress reports on the investigation. (At least yearly.)
☐ Yes ☐ No ☐ N/A	Any deviation from the investigational plan to protect the life or physical well-being of a participant in an emergency. (As soon as possible, but in no event later than 5 working days after the emergency occurred unless required sooner by sponsor.)
☐ Yes ☐ No ☐ N/A	Emergency use of an investigational device without obtaining informed consent (Within 5 working days after

	the use occurs unless required sooner by sponsor.)
☐ Yes ☐ No ☐ N/A	A final report. (Within 3 months after termination or completion of the investigation or the investigator's part of the investigation unless required sooner by sponsor.)
	Investigators prepare and submit the following reports to the IRB:
☐ Yes ☐ No ☐ N/A	Any unanticipated adverse device effect occurring during an investigation. (As soon as possible, but in no event later than 5 working days after first learning of the effect.)
☐ Yes ☐ No ☐ N/A	Progress reports on the investigation. (At least yearly.)
☐ Yes ☐ No ☐ N/A	Any deviation from the investigational plan to protect the life or physical well-being of a participant in an emergency. (As soon as possible, but in no event later than 5 working days after the emergency occurred.)
☐ Yes ☐ No ☐ N/A	Emergency use of an investigational device without obtaining informed consent (Within 5 working days after the use occurs.)
☐ Yes ☐ No ☐ N/A	A final report. (Within 3 months after termination or completion of the investigation or the investigator's part of the investigation.)
11. IND Sponsor-Investigator Responsibilities/Requirements	
☐ Yes ☐ No ☐ N/A	Is a copy of the Original IND application to the FDA on file?
☐ Yes ☐ No ☐ N/A	Are ALL amendments to the IND on file?
☐ Yes ☐ No ☐ N/A	Are ALL annual reports to the IND on file?
☐ Yes ☐ No ☐ N/A	Are ALL safety reports on file?
☐ Yes ☐ No ☐ N/A	Is ALL correspondence with the FDA on file?
☐ Yes ☐ No ☐ N/A	Is there a form 1571 on file to accompany all of the above FDA correspondence?
☐ Yes ☐ No ☐ N/A	Is there a Financial Disclosure Form (Form 3454 or 3455) on file for each investigator listed on the FDA Form 1572 or for each person who signed an Investigator Agreement?
☐ Yes ☐ No ☐ N/A	Is there a signed FDA Form 3674 – Certificate of Registration to ClinicalTrials.gov on file? A FDA Form 3674 should be on file for each applicable study.
☐ Yes ☐ No ☐ N/A	The investigator maintains on file information pertaining to the financial interests of clinical investigators for 2 years after the date of approval of the application
☐ Yes ☐ No ☐ N/A	The investigator selects qualified investigators
☐ Yes ☐ No ☐ N/A	The investigator provides participating investigators with the information they need to conduct an investigation properly
☐ Yes ☐ No ☐ N/A	The investigator ensures that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND
☐ Yes ☐ No ☐ N/A	The investigator maintains an effective IND with respect to the investigations
☐ Yes ☐ No ☐ N/A	The investigator ensures that FDA is promptly informed of significant new adverse effects or risks with respect to the drug
☐ Yes ☐ No ☐ N/A	The investigator ensures that all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug
☐ Yes ☐ No ☐ N/A	The investigator selects only investigators qualified by training and experience as appropriate experts to investigate the drug
☐ Yes ☐ No ☐ N/A	The investigator ships investigational new drugs only to investigators participating in the investigation
	Before permitting an investigator to begin participation in an investigation, the investigator obtains the following:
☐ Yes ☐ No ☐ N/A	A signed investigator statement (Form FDA-1572)
☐ Yes ☐ No ☐ N/A	A CV or other statement of qualifications (biosketch/resume) of the investigator showing the education, training, and experience that qualifies the investigator as an expert in the clinical investigation of the drug for the use under investigation
☐ Yes ☐ No ☐ N/A	Sufficient accurate financial information to allow the investigator to submit complete and accurate certification or disclosure statements
☐ Yes ☐ No ☐ N/A	The investigator selects a monitor qualified by training and experience to monitor the progress of the investigation
☐ Yes ☐ No ☐ N/A	The investigator provides each participating clinical investigator an investigator brochure
☐ Yes ☐ No ☐ N/A	The investigator ensures, as the overall investigation proceeds, that each participating investigator is informed of new observations discovered by or reported to the investigator on the drug, particularly with respect to adverse effects and safe use
☐ Yes ☐ No ☐ N/A	The investigator monitors the progress of all clinical investigations being conducted under the IND
☐ Yes ☐ No ☐ N/A	If the investigator discovers that an investigator is not complying with the signed agreement (Form FDA-1572), the general investigational plan, or other applicable requirements; the investigator promptly either secures compliance or

	discontinues shipment of the investigational new drug to the investigator and ends the investigator's participation in the investigation
☐ Yes ☐ No ☐ N/A	If the investigator's participation in the investigation is ended, the investigator ensures that the investigator dispose of or returns the investigational drug and notifies the FDA
☐ Yes ☐ No ☐ N/A	The investigator reviews and evaluates the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator(s)
	If the investigator determines that the investigational drug presents an unreasonable and significant risk to participants, the investigator:
☐ Yes ☐ No ☐ N/A	Ensures discontinuation of those investigations that present the risk
☐ Yes ☐ No ☐ N/A	Notifies the FDA, all institutional review boards, and all investigators who have at any time participated in the investigation of the discontinuance
☐ Yes ☐ No ☐ N/A	Ensures the disposition of all stocks of the drug outstanding
☐ Yes ☐ No ☐ N/A	Furnishes the FDA with a full report of the investigator's actions
☐ Yes ☐ No ☐ N/A	The investigator maintains adequate records showing the receipt, shipment, or other disposition of the investigational drug, including, as appropriate, the name of the investigator to whom the drug is shipped, and the date, quantity, and batch or code mark of each such shipment
☐ Yes ☐ No ☐ N/A	The investigator retains these records and reports for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified
☐ Yes ☐ No ☐ N/A	The investigator retains reserve samples of any test article and reference standard identified in, and used in any bioequivalence or bioavailability studies and release the reserve samples to the FDA upon request
☐ Yes ☐ No ☐ N/A	The investigator retains each reserve sample for a period of at least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not approved, at least 5 years following the date of completion of the bioavailability study
☐ Yes ☐ No ☐ N/A	The investigator permits, upon request from any properly authorized officer or employee of the Food and Drug Administration, at reasonable times, such officer or employee to have access to and copy and verify any records and reports relating to a clinical investigation being conducted under the IND
☐ Yes ☐ No ☐ N/A	The investigator submits, upon written request by the FDA, the records or reports (or copies of them) to the FDA
☐ Yes ☐ No ☐ N/A	The investigator discontinues shipments of the drug to any investigator who has failed to maintain or make available records or reports of the investigation as required
	If an investigational new drug is a substance listed in any schedule of the Controlled Substances Act (21 U.S.C. 801; 21 CFR part 1308), the investigator ensures:
☐ Yes ☐ No ☐ N/A	Upon the request of a properly authorized employee of the Drug Enforcement Administration of the U.S. Department of Justice, all records concerning shipment, delivery, receipt, and disposition of the drug, which are required to be kept be made available by the investigator to whom the request is made, for inspection and copying
☐ Yes ☐ No ☐ N/A	That adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution
☐ Yes ☐ No ☐ N/A	The investigator ensures the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated

Participant Files
(Complete for sample of enrolled participants. If participant files are not accessible, disregard this section.)

Principal Investigator	
Protocol #/Study Title	
Total Sample Reviewed	
Participant IDs	
Name of Person Completing Checklist	
Date Completed	

1. Recruitment	
☐ Yes ☐ No ☐ N/A	Are all the recruitment methods/processes being followed in accordance with the IRB approved protocol?
☐ Yes ☐ No ☐ N/A	Have ALL recruitment materials (e.g., advertisements and telephone scripts) been approved by the IRB? Note: All recruitment materials must be approved prior to use and must be re-approved at the time of continuing review.
2. Participant Selection	
☐ Yes ☐ No ☐ N/A	Is source documentation on file to verify inclusion/exclusion criteria?
☐ Yes ☐ No ☐ N/A	There is a completed eligibility checklist
☐ Yes ☐ No ☐ N/A	The eligibility criteria checklist includes dated signature/initials of the person making the eligibility determination
☐ Yes ☐ No ☐ N/A	For participants who did not meet eligibility (e.g. screen-failures), identifiable information was destroyed or authorization was obtained to keep participant information
3. Consent	
☐ Yes ☐ No ☐ N/A	Was the consent process conducted per the IRB-approved protocol?
☐ Yes ☐ No ☐ N/A	The number of participants who have signed consent forms, i.e., enrolled, is no greater than the IRB-approved sample size/enrollment
☐ Yes ☐ No ☐ N/A	Investigators obtained consent from each participant prior to the start of any study procedures
☐ Yes ☐ No ☐ N/A	Original copies (not photo copies) of all consent forms signed and dated by participants are on file
☐ Yes ☐ No ☐ N/A	Valid IRB-approved consent forms were used
☐ Yes ☐ No ☐ N/A	All pages of the consent forms are on file for each participant
☐ Yes ☐ No ☐ N/A	All yes/no, checkboxes, or similar options on the consent forms are completed and/or initialed
☐ Yes ☐ No ☐ N/A	Consent forms are free of any handwritten changes or corrections
☐ Yes ☐ No ☐ N/A	The participant/participant representative signed his/her own consent forms. (Exceptions: IRB-approved surrogate)
☐ Yes ☐ No ☐ N/A	The participant/participant representative received a copy of the consent form
☐ Yes ☐ No ☐ N/A	The participant's/participant representative's receipt of a copy of the consent form is documented, e.g., Enrollment Log
☐ Yes ☐ No ☐ N/A	An IRB-approved study representative obtained consent for all participants
☐ Yes ☐ No ☐ N/A	An IRB-approved study representative signed/dated the consent form
☐ Yes ☐ No ☐ N/A	An IRB-approved study representative entered the same date as the participant/participant representative on the consent form
☐ Yes ☐ No ☐ N/A	Were non-English speaking subjects enrolled?
☐ Yes ☐ No ☐ N/A	If non-English speaking subjects were enrolled, was the IRB-approved process for enrolling non-English speaking subjects followed?
☐ Yes ☐ No ☐ N/A	If Short Form Consent is implemented, a witness signed and dated the consent form
☐ Yes ☐ No ☐ N/A	Consent is obtained from enrolled minors that reach local age of majority during the study
☐ Yes ☐ No ☐ N/A	Waiver of the requirement to obtain consent and/or alteration of consent process on file
☐ Yes ☐ No ☐ N/A	Wavier of documentation (signature requirement) on file
4. Prompt Reporting Requirements	
☐ Yes ☐ No ☐ N/A	All prompt reporting requirements have been fulfilled
5. Data Collection Source Documents	
☐ Yes ☐ No ☐ N/A	Data collection complete/accurate for each participant. (e.g. no blank fields/missing data)
☐ Yes ☐ No ☐ N/A	Source documentation is available to support data entry
☐ Yes ☐ No ☐ N/A	The source documentation/CRF for each participant includes dated signature/initials of the person obtaining the

	information for each participant (i.e. physical or clinical assessment pages)
☐ **Yes** ☐ **No** ☐ **N/A**	Changes/cross-outs, additional comments (if any) in participant files routinely initialed and dated
☐ **Yes** ☐ **No** ☐ **N/A**	For any changes/cross-outs being made, the original entry is still legible. (e.g. use of white-out or pencil erased entries is not acceptable)
6. Drug/Device Dispensing Accountability (for non Investigational drugs, biologics, devices)	
Note: This section may not apply to your study if an investigational product, or "test article," is not part of the study. If that is the case, Check "N/A" in section 6.	
Who is responsible for drug/device accountability? ☐ Study Site ☐ Research Pharmacy ☐ Other: ☐ N/A	
If study site is responsible for drug/device accountability, complete the section below.	
☐ **Yes** ☐ **No** ☐ **N/A**	Is documentation on file for receipt of the investigational product?
☐ **Yes** ☐ **No** ☐ **N/A**	Is there documentation of drug/biologic/device use for each subject (e.g., drug accountability log, study file notation)?
☐ **Yes** ☐ **No** ☐ **N/A**	Is there documentation of return of drug/biologic/device from the subject to the study site?
☐ **Yes** ☐ **No** ☐ **N/A**	Is there documentation of the return of the drug to the sponsor/manufacturer/research pharmacy or docuemtnation of the destruction of the drug/biologic device?
☐ **Yes** ☐ **No** ☐ **N/A**	Have there been any other events (e.g., drug/biologic dosing errors or device malfunctions) to date?
☐ **Yes** ☐ **No** ☐ **N/A**	Have the events in #61 been reported to the IRB as unanticipated problems?
7. Laboratory Documentation	
Note: This section may not apply to your study if an investigational product, or "test article," is not part of the study. If that is the case, Check "N/A" in section 7.	
☐ **Yes** ☐ **No** ☐ **N/A**	Is Laboratory Certification (CLIA/CAP) current and on file?
☐ **Yes** ☐ **No** ☐ **N/A**	Are all out-of-range laboratory values marked as to their clinical significance?
☐ **Yes** ☐ **No** ☐ **N/A**	Are laboratory reference ranges (normal values) on file?