Regulatory Documents (FDA, NIH)

☐ Not applicable

List required regulatory documents as applies to study, including expected documents as applies to good clinical practices or sponsor agreements

Document	Notes	On File? IRB	On File? PI
FDA 1572/1571: signed, dated		☐	☐
Required CVs: current and accurate		☐	☐
Lab Certifications/Normal Values		☐	☐
Investigator Brochure		☐	☐
Current Protocol		☐	☐
Current SOP/MOO (if available)		☐	☐
Monitoring Log		☐	☐
CRFs – current, blank		☐	☐
Source Documents – Source log		☐	☐
Roles & Responsibilities Log		☐	☐
Staff Signature Log		☐	☐
		☐	☐
		☐	☐
		☐	☐

Scientific Review *if separate from IRB review*

☐ Not applicable

☐ Specify Department:

For each scientific review, list what auditor should verify based on institutional and sponsor policies and where documentation can be found if electronically stored.

Document	Date	Notes	On File? IRB	On File? PI
			☐	☐
			☐	☐
			☐	☐
			☐	☐

→ **NOTES:**

IRB Review and Approval Documentation

For each submission type and review (initial review, continuing reviews, amendments, unanticipated events), list the required documents the IRB and PI must maintain: complete submission, IRB action letters, PI responses, pertinent correspondence, IRB final approval letter (or other final determination) and stamped approved consent/assent forms (for each group if applicable).

		Approved Protocol and Consent Forms			On File?	
Document	**Date**	**Approval**	**Activation**	**Expiration**	**IRB**	**PI**
					☐	☐
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→ **NOTES:**

Regulatory and IRB Documents

	YES	NO
Does the PI have all required Regulatory documents on file? → *If NO*, PI must obtain copies/originals of missing documents and file, or write memo-to-file	☐	☐
Does the PI have all required Scientific Review documents on file? → *If NO*, PI must obtain copies/originals of missing documents and file, or write memo-to-file	☐	☐
Does the PI have all required IRB documents on file? Reference 'Review History' → *If NO*, PI must obtain copies/originals of missing documents and file, or write memo-to-file	☐	☐

→ **NOTES/Observations:**

Protocol Review, Approvals and Outside Reports

	YES	NO
Has the protocol ever expired or placed on hold/suspended? Reference 'Review History' → *If YES*, specify time frames:	☐	☐
Was there any protocol activity or enrollment during expired time frames? → *If YES*, PI must document for study records and report to IRB per institutional/sponsor policy	☐	☐
Are there any outside monitoring reports/letters and/or FDA annual reports? → *If YES*, PI must submit copies for IRB files.	☐	☐

→ **NOTES/Observations:**

Reportable Unanticipated Events: Documentation and Reporting

	YES	NO
▪ **Have all reportable events been identified, documented and reported properly?** *If NO*, please specify below:	☐	☐

- ▪
- ▪
- ▪

	YES	NO
▪ **For each event/problem, was there adequate follow-up and resolution?** *If NO*, please specify below:	☐	☐

- ▪
- ▪
- ▪

→ **NOTES/Observations:**

Deviations and Exceptions: Identification, Documentation and Reporting

	YES	NO
▪ **Have all deviations/exception been identified, documented & reported properly?** *If NO*, please specify below:	☐	☐

- ▪
- ▪

	YES	NO
▪ **For each deviation/exception, was there adequate follow-up and resolution?** *If NO*, please specify below:	☐	☐

- ▪
- ▪

→ **NOTES/Observations:**

Informed Consent and Assent: Content and Process as Approved

- List the consent and assent forms used for this study:
  -
  -

	YES	NO	N/A
▪ Is there an appropriate consent/assent form for each subject group?	☐	☐	☐
▪ Is each consent/assent form formatted for the specific subject group (e.g. signatures)?	☐	☐	☐

For each consent/assent form:

▪ Is the language clear and understandable for the subject/family?	☐	☐	☐
▪ Is the consent form translated into other languages?	☐	☐	☐
▪ Does the form adequately explain all study procedures?	☐	☐	☐
- *If applicable,* are all procedures properly labeled experimental?	☐	☐	☐
▪ Will the signed form be filed in the subject's medical record?	☐	☐	☐
▪ Will any identifying info (PHI) be shared with anyone outside CHB?	☐	☐	☐
- *If YES*, is this clearly stated in the consent/assent form?	☐	☐	☐
▪ Does the form address include all required elements?	☐	☐	☐

☐Research Study	☐Confidentiality	☐May discontinue/PI may terminate
☐Purpose of study	☐In event of injury	☐Any subject costs
☐Risks & Benefits	☐Emergency contact	☐New findings
☐Alternatives	☐Study is voluntary	☐# of subjects

→ **NOTES/Observations:**

Informed Consent and Assent: Compliance

Complete following section after conducting on-site subject file/record review (reference Subject Audit Forms)

	YES	NO	Specify/Notes
▪ Is a copy of signed consent form given to each subject?	☐	☐	
▪ Do subjects/parents date their own signature?	☐	☐	
▪ Is consent process documented anywhere else? - e.g. progress notes, visit notes, consent source document	☐	☐	
▪ Does PI maintain original, signed copies?	☐	☐	

→ **NOTES/Observations:**

Recruitment Method and Subject Compensation

Approved Protocol:

Recruitment Methods and Materials: ☐ None

- ☐ Advertisements:
- ☐ Internet:
- ☐ Flyer/Posters:
- ☐ Mailed Letters*:
- ☐ Phone Call*:
- ☐ Other:

*How are subjects identified?

- ☐ Medical Records Review
- ☐ Database Review, specify
- ☐ Outpatient/Inpatient Visits
- ☐ MD Referrals
- ☐ Other

Subject Compensation: ☐ None

- ☐ Gift Certificate → Specify:
- ☐ Gift (e.g. toy) → Specify:
- ☐ Taxi or Parking Vouchers → Specify:
- ☐ Transportation → Specify:
- ☐ Food/Meals → Specify:
- ☐ Money → Specify:

Subject Population
Check all groups eligible for this study:

- ☐ Healthy Controls
- ☐ Pregnant Women
- ☐ Mentally Handicapped
- ☐ Wards of State
- ☐ Employees/Staff
- ☐ Students
- ☐ Fetus → Does this meet the Fetal Statute? ☐ Yes ☐ No
- ☐ Newborn/Infant
- ☐ Children (between 2 and 12 years)
- ☐ Adolescents (between 13 and 18 years)
- ☐ 18 – 21 years of age
- ☐ 22 – 35 years of age
- ☐ Over 35 years

During Study Review:

	YES	NO	Specify/Notes
▪ Is recruitment method adequate/working?	☐	☐	
▪ Are recruitment efforts tracked?	☐	☐	
▪ Is compensation documented when given?	☐	☐	

Subject Enrollment

As PI reported/on file	Year 1	Year 2	Year 3	Year 4	Year 5
Enrolled in Past Year					
Enrolled in Total					
Subjects still Needed					

Data Safety Monitoring Board and Plan

	YES	NO	N/A
▪ Does this study require a DSMP? Check yes if any of the following criteria are met.	☐	☐	☐
☐Prospective clinical trial involving human subjects designed to answer questions re: effect or impact of biomedical or behavioral intervention (e.g. drugs, treatment, devices, behavioral or nutritional strategies)			
☐Clinical Trials: Phase I, II or III			
☐Pilot interventions with higher level risk			
☐Associated with Clinical Research Program			
▪ Are the members of the DSMB appropriate, with adequate expertise?	☐	☐	☐
▪ Are the members of the DSMB independent (not related to study conduct)?	☐	☐	☐
▪ If sponsored research, is at least one member of DSMB independent of company?	☐	☐	☐
▪ Does the DSMP include the following four basic features?	☐	☐	☐

☐ Process to monitor research progress and patient safety
- Who monitors trial?
- What specific outcomes do they look for?
- How often is data examined?
- What procedure is in place to ensure adequate and timely feedback to researchers and medical decision-makers for prompt response?
- Is the oversight/supervisory role of PI/sponsor appropriate?
- If applicable, what are procedures for coordinating multi-center research?

☐ Process for detecting and reporting adverse events (AEs)
- Scale for grading severity of AE
- Scale for estimating the relationship of AE to participation in the trial
- Plan for detection and reporting of unanticipated events
- Plan for annual reporting of events
- An overall plan for safety review

☐ Process for reporting actions resulting in study suspension to PI, Sponsor and IRB in a timely fashion.
☐ Process for assuring data accuracy and protocol compliance

During Study Review

	YES	NO	Specify/Notes
▪ Is Data Safety Monitoring Board and Plan adequate?	☐	☐	
▪ Has PI followed DSMP?	☐	☐	
▪ Have all events been submitted to DSMB?	☐	☐	
▪ Have all DSMB reports been submitted to CCI/IRB?	☐	☐	

→ **NOTES/Observations:**

Protocol Adherence

Is the following general information still the same as last reviewed/approved?

→ *If NO*, PI must submit amendment/notification memo to CCI/IRB to update information as specified/noted.

	YES	NO	Specify/Notes
▪ Sponsor & Funding Source	☐	☐	
▪ Total Subject Enrollment (N)	☐	☐	
▪ Study Duration (anticipated)	☐	☐	
▪ Study Resources & Support	☐	☐	
▪ Subject Time Commitment	☐	☐	
▪ Research Staff & Training	☐	☐	

→ **NOTES/Observations:**

Overall, is the PI/staff complying with the following study procedures as last approved?

→ *If NO*, PI must document and report deviation according to CCI/IRB policy.
PI must consider whether to amend protocol accordingly or comply with protocol as approved.

	YES	NO	Specify/Notes
▪ Subject Enrollment (exceeded?)	☐	☐	
▪ Recruitment & Compensation	☐	☐	
▪ Informed Consent Process	☐	☐	
▪ Consent & Document Storage	☐	☐	
▪ Data Safety Monitoring Plan	☐	☐	
▪ Subject Eligibility Criteria	☐	☐	
▪ Study Visits and Procedures - Are unapproved procedures conducted?	☐	☐	

→ **NOTES/Observations:**

Research Staff: Communication, Coordination, Training and Education

	YES	NO	Specify/Notes
▪ Is research staff adequately trained re: study?	☐	☐	
▪ Is there a staff log or responsibilities log?	☐	☐	
▪ Is there regular communication between PI and staff?	☐	☐	

Study Documentation, Source Verification and General Organization

	YES	NO	Specify/Notes
▪ Are all necessary data points collected?	☐	☐	
▪ Is data consistently captured and documented?	☐	☐	
▪ Is data captured on Case Report Forms (CRFs)?	☐	☐	
▪ Are source documents available to verify data?	☐	☐	
▪ Are documents organized, available and complete?	☐	☐	
▪ Are corrections documented to ensure audit trail?	☐	☐	

→ **Subjects Audited** (reference specific Subject Audit Forms if applicable):

→ **NOTES/Observations:**