Regulatory Documents

☐ Not applicable

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

Scientific Review

☐ Specify Department:

For each scientific review, include: reviewer worksheets and comments, PI responses, documentation of final approval of review (authorized signature, department letter, etc) indicating resolution of raised concerns.

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

→ **NOTES:**

CCI/IRB Review

For each review, include: submission, CCI/IRB action, PI Responses, pertinent correspondence, CCI/IRB final approval, and consent/assent forms. For each submission, ensure that the appropriate attachments (e.g. consent/assent forms, recruitment materials, surveys) are included and reviewed.

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

Recruitment and Compensation

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:	

Data Safety Monitoring Board (DSMB) and Plan (DSMP)

	YES	NO	N/A
▪ Does this study require a DSMP? Must check yes if any of the following criteria are met.	☐	☐	☐
▪ Are the members of the DSMB appropriate, with adequate expertise?	☐	☐	☐
▪ Are the members of the DSMB independent (not related to study conduct or interests)?	☐	☐	☐
▪ If sponsored research, is at least one member of DSMB independent of company?	☐	☐	☐
▪ Does the DSMP include the following four basic features?	☐	☐	☐

☐ 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 General Clinical Research Center (GCRC)

- ▪ If GCRC waives DSMP requirement, explain:

☐ 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

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

Subject Enrollment

As PI reported ….	Year 1	Year 2	Year 3	Year 4	Year 5
Enrolled in Past Year					
Enrolled in Total					
Subjects still Needed					

Informed Consent and Assent: Content and Process

- 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?	☐	☐	☐
- See Informed Consent Requirements Checklist			

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:**

CCI/IRB Review

New Protocol: was the following info accurate, complete and included with the CCI/IRB application?

	NA	YES	NO	Specify/Notes
▪ Scientific Review - Reviewer Worksheets - PI Responses, as applicable - Clear resolution of reviewer concerns/issues - Authorized signatures	☐	☐	☐	
▪ Protocol (or Part B)	☐	☐	☐	
▪ Protocol Application: - Parts A – D: All protocols - Parts E (drugs) or F (devices) - Part G: Clinical Imaging for Research Purposes - Part H: Use of Radiation and/or MRI - Part I: Genetic Research: Part I - Part J: Waiver of Parental Permission - Part K: GCRC - Part L: Pregnant women and Fetuses - Part M: Prisoners - Part N: Research at Waltham	☐	☐	☐	
▪ Informed Consent/Assent Forms	☐	☐	☐	
▪ Study Appendix Materials As applicable, including: - Sponsor Protocol - Investigator Brochure (3 copies) - Federal Grant Application (3 copies) - Surveys, Questionnaires, Assessment - Recruitment letters, posters, ads, fliers, etc. - Subject documents: reminders, thank-you, etc - Study flow charts, schemas	☐	☐	☐	
▪ Deviations & Exceptions	☐	☐	☐	
▪ Amendments & Revisions As applicable, including: - revised/marked up Consent & Assent forms - revised/marked up study materials - new Consent and Assent forms - new study materials	☐	☐	☐	
▪ PI Responses, *if applicable*	☐	☐	☐	
▪ Pertinent Correspondence	☐	☐	☐	

	YES	NO
▪ **In general, were all procedures and issues adequately described and submitted for review?** *If NO*, please explain below:	☐	☐

▪

→ **NOTES/Observations:**

CCI/IRB Review

Continuing Reviews/3-Yr Rewrites: was the following info accurately reported, updated and submitted with each Continuing Review or New Protocol/3-Yr Rewrite Application?

	NA	YES	NO	Specify/Notes
▪ Subject Enrollment	☐	☐	☐	
▪ Executive Research Summary, *or* Updated Protocol or Part B	☐	☐	☐	
▪ Data Safety Monitoring Reports	☐	☐	☐	
▪ Outside Monitoring Reports	☐	☐	☐	
▪ Serious Adverse Events, and/*or* Unanticipated Problems	☐	☐	☐	
▪ Deviations & Exceptions	☐	☐	☐	
▪ Amendments & Revisions As applicable, including: - revised Consent/Assent forms (tracked changes) - revised Study Materials forms (tracked changes) - new Consent and Assent forms - new study materials	☐	☐	☐	
▪ Currently used Consent/Assent	☐	☐	☐	
▪ Conflict of Interests (changes)	☐	☐	☐	
▪ Research Staff (changes)	☐	☐	☐	
▪ Risk/Benefit (changes)	☐	☐	☐	

→ **NOTES/Observations:**

Amendments: was the following info accurate, complete and/or submitted w/each Amendment Application?

	NA	YES	NO	Specify/Notes
▪ Amended study materials As applicable, include: - revised Consent/Assent forms (tracked changes) - revised Study Materials forms (tracked changes) - new Consent and Assent forms - new study materials	☐	☐	☐	
▪ Risk/Benefit (change)	☐	☐	☐	
▪ Scientific Review, *as applicable*	☐	☐	☐	

→ **NOTES/Observations:**

CCI/IRB Review

	YES	NO
Has the protocol ever expired or been placed on hold/suspended? → *If YES*, specify time frames:	☐	☐
Was there any protocol activity, recruitment or enrollment during expired time frames? → *If YES*, PI must document as a Significant Deviation and report to CCI/IRB.	☐	☐
Are there any outside monitoring reports/letters and/or FDA annual reports? → *If YES*, PI must submit copies for CCI/IRB files.	☐	☐

→ **NOTES/Observations:**

Regulatory and CCI/IRB Documents

	YES	NO
Does the PI have all required Regulatory documents on file? Reference 'Review History' → *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? Reference 'Review History' → *If NO*, PI must obtain copies/originals of missing documents and file, or write memo-to-file	☐	☐
Does the PI have all required CCI/IRB documents on file? Reference 'Review History' → *If NO*, PI must obtain copies/originals of missing documents and file, or write memo-to-file	☐	☐
Does the PI use CCI Tracking Log, or Study Document Log? → *If NO*, recommend if deemed necessary	☐	☐

→ **NOTES/Observations:**

Data Safety Monitoring Board and Plan

	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:**

Recruitment Method and Subject Compensation

	YES	NO	Specify/Notes
▪ Is recruitment method adequate/working?	☐	☐	
▪ Are recruitment efforts tracked (e.g. recruitment log)?	☐	☐	
▪ Is subject compensation adequate/fair?	☐	☐	
▪ Is compensation documented when given?	☐	☐	

→ **NOTES:**

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 easily available to verify data?	☐	☐	

	YES	NO	Specify/Notes
▪ Are documents organized, available and complete?	☐	☐	
▪ Are corrections documented to ensure audit trail?	☐	☐	

Informed Consent and Assent: Content and Process

	YES	NO	Specify/Notes
▪ Is a copy of signed consent form given to 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?	☐	☐	

Adverse and Unanticipated Events: Documentation and Reporting

	YES	NO
▪ **Have all adverse 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:	☐	☐

- ▪
- ▪
- ▪

Deviations and Exceptions: Identification, Documentation and Reporting

	YES	NO
▪ **Have all deviations/exception been identified, documented and 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:	☐	☐

- ▪
- ▪

	YES	NO
▪ **Was PI/staff aware of deviation policy?**	☐	☐
▪ **Was PI/staff aware of exception policy?**	☐	☐