DEPARTMENT OF NEUROSCIENCES
Regulatory Compliance Review Tool

Protocol Title and IRB Number:		**Study Type:**	☐Industry ☐Government ☐PI initiated
Principal Investigator:			
Research Unit:		**Source Type:**	☐EPIC ☐Paper ☐Velos ☐Other_____
Review Dates:			

1. Clinical Site Personnel Present or Assisting with Study Review

Name:	Study Role:

REGULATORY BINDER – INTERNAL REVIEW

Review Category	Criteria *Documents may be retained in hardcopy or electronic format	Yes	No / Deficient	N/A
Regulatory Oversight Documents & Processes	**Protocol and Amendments**			
	A current IRB-approved copy of the protocol is on file			
	All previous versions of the protocol are on file.			
	Protocol/Protocol Amendment(s) Signature Pages			
	Approvals for any protocol			
	Informed Consent Documents			
	A current and IRB-approved copy of the informed consent form(s) (ICF) is on file in the regulatory binder.			
	Informed Documentation of the Informed Consent Process is on file in the subjects' charts.			
	Approvals for any consent/assent amendments are present in ISF binder.			
	IRB Documentation			

	Criteria *Documents may be retained in hardcopy or electronic format	Yes	No / Deficient	N/A
	IRB Federal-Wide Assurance Number (FWA)*			
	IRB Approval and Correspondence (filed in Reg. Binders)			
	Approvals for any advertisements, participants handouts dosing instructions, etc. (all participant facing materials)*			
	IRB approval letters specify which versions of the protocol and/or ICF were approved. If approval letters are from CIRB, are these uploaded to UCSD Kuali Research.			
	Continuing review approval(s) are present (annually) from CIRB or LIRB as applicable. If from CIRB, are approvals uploaded to UCSD Kuali Research.			
	Monitoring			
	Monitoring/audit reports are on file.			
	Action items from previous monitoring/audit reports resolved.			
	Clinical Investigator Brochure			
	[Investigator brochures or package inserts are current and available for investigational products. Documentation of IRB submission is present (if applicable).			
	Investigator Brochure(s) acknowledgment pages.			
	Laboratory Certifications			
	Note to file indicating that UCSD does not provide list of laboratory ranges			
	Copy of certifications and accreditations of labs used for research (CAP, CLIA, CA license)			
	Lab Director CV			
	Investigational Product			
	IP shipping records for any new IP shipped are on file.			
	Certificates of analysis for any new batches of IP shipped are on file as applicable			

	Criteria *Documents may be retained in hardcopy or electronic format	Yes	No / Deficient	N/A
	Pharmacy Manuals are all file in ISF or NTF documenting location of documents			
	All newsletters file in ISF			
Comments				
Study Staff Qualifications	**Investigator Qualification Documentation**			
	Current signed and dated CVs or biosketches are up-to-date for the Principal Investigator and staff listed on the Delegation of Authority Log.			
	Appropriate clinical licenses are up-to-date for Principal Investigator and all sub-investigators and clinicians as listed on the Delegation of Authority Log.			
	Clinical Research and Study Training			
	Up-to-date certificates of Human Subjects Protection Training (BMR) for all study personnel, including PI, Sub-Is/Co-Is, CRCs, Research Nurses, Lab Assistants, etc. (this is a UCSD requirement)			
	Up-to-date certificates of GCP training for all study personnel, including PI, Sub-Is/Co-Is , CRCs, Research Nurses, Lab Assistants, etc.			
	Up-to-date certificates of HIPAA training for all study personnel, including PI, Sub-Is/Co-Is , CRCs, Research Nurses, Lab Assistants, etc. (this is a UCSD requirement)			
	SIV training logs available for review			
	SIV report available for review			
	Certificate of IATA training for individuals shipping specimens (as applicable).			
	Other Training: Up-to-date documentation of study-specific training for all relevant personnel is up-to-date.			
Comments				
Study Operations/ Facilities Oversight	Documentation of internal correspondence is present and current (e.g. weekly study meeting minutes).			

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	Documentation of external correspondence is present and current (e.g. important communications with Program Manager, DSMB, FDA, Sponsor, and CRA Monitor or others).			
	Study facilities continue to be appropriate for the conduct of the study.			
	The PI is adequately supervising the conduct of the study (PI oversight) in accordance with ICH GCP E6 (R2.			
	The study continues to have adequate operational requirements or standards (i.e. ACTRI resources).			
	A review of the signed ICFs indicated that all subjects were consented appropriately and all ICF fields were accurately completed. Verify that re-consent was obtained is applicable.			
	IP inventory matches subject IP accountability log (often maintained as a balance/forward log at the pharmacy or CRC, depending on who is managing drug.			
	Verify that temperature logs are available and up-to-date (if IP not managed by IDS pharmacy)			
	Study supply inventory is adequate and not expired (lab kits, electronic devices, etc.).			
Comments				
Study Logs and Forms	**Delegation of Authority Log**			
	The Delegation of Authority Log is present and accurate.			
	FDA Documents, as applicable			
	FDA approval document for test article.			
	FDA correspondence log.			
	The FDA 1572 form is current and on file (original).			
	Signed Financial Disclosure Forms for PI, and Sub-Is.			
	Specimen Tracking			
	Copies of central laboratory requisition forms available if kept in regulatory binder.			

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	Subject Study Logs			
	A subject screening log is present and accurate.			
	A subject enrollment log is present and accurate.			
	Subject Consent Log (either stand alone or part of the enrollment log)			
	Confidential subject identification code linking subject numbers to subject names/contact info is up-to-date. (must be kept separately) .			
	Training Logs			
	Sponsor provided training log signed/dated by PI and initial by trainees			
	UCSD required trainings (HIPAA and BMR)			
	Department and study SOP training. Signed and dated by PI and initialed by trainee.			
	Monitoring Logs			
	Site Visit Monitoring Logs available and up-to-date			
	Study Deviation and AE/SAE Logs			
	Protocol Violations and Deviations Log is available and up-to-date. Ensure reporting dates as required by sponsor or regulatory agencies are included.			
	AE/SAE log is available and up-to-date. Ensure reporting dates as required by sponsor or regulatory agencies are included			
	SUSARS (IND) Safety Reports assessed by PI and on file* Ensure reporting dates as required by sponsor or regulatory agencies are included.			
	Reports are on file for any events that required expedited reporting to regulatory authorities.			
	Sponsor Specific Forms/Documents (All Filed)			
	Data Safety Monitoring Board Plan (if not included as part of study protocol)			
	DSMB/DCM recommendations and correspondence.			
	DSMB/DCM meeting minutes, if different from above.			

Comments				
	Criteria *Documents may be retained in hardcopy or electronic format	**Yes**	**No / Deficient**	**N/A**
	Data Quality			
Data Quality	Both paper and electronic Case Report Form (CRF) templates have a form title, version date/version number, and page numbers, and have fields for subject number, visit number, visit date, and initials of staff collecting data.			
	The electronic data capture system (EDC) is compliant with 21CFR11. (only for FDA studies)			
	The EDC is capturing all protocol-required data fields.			
	Appropriate tracking of adverse events, protocol deviations, and GCP adherence observed through study.			
	SOPs are being followed to ensure continuous QA/QI of study data and site operations.			
	SOPs are being followed to ensure data are collected consistently across subjects. (i.e. do all subject charts within a study follow same structure).			
Comments				

INDIVIDUAL PARTICIPANT RESEARCH CHART– INTERNAL REVIEW

PARTICIPANT REVIEWED PID # IRB#	**FROM VISIT – TO VISIT**			**SUBJECT STATUS** □ Screening □ Screen Fail □ Active □ Lost to F/U or Withdrawn X Completed
Chart reviewed: □ Participant □ Study Partner □ Genetics □ PK/PD □ Imaging □ Other:_____				
***Use one individual participant research chart review form per subject**				
SUMMARY OF FINDINGS	**Y**	**N**	**N/A or Not Reviewed**	**COMMENTS**
Signed original informed consent/ assent appropriately obtained and documented, including all IRB approved versions that require re-consent				
All assessments/study activities completed after date/time of ICF consent				
Signed original copy of HIPAA Research Authorization form as applicable See UCSD HIPAA.				
Copy of Bill of Rights (does not need to be signed by subject) only required if the study is a medical experiment per CA law				
Eligibility checklist (inclusion/exclusion criteria) – signed by PI				
Participant is eligible based on source documentation				
Concomitant meds allowable for entry into study and remain allowable per protocol throughout study – refer to subject's concomitant med log				•
Clinical and laboratory evaluations obtained as per protocol; values allowable per protocol a. Copies of laboratory requisition forms available b. Lab reports available, assessed, and signed by PI within 3-5 days of receipt				
Study investigators are reviewing and signing lab reports within 24 hours if significantly abnormal				

SUMMARY OF FINDINGS	Y	N	N/A or Not Reviewed	COMMENTS
ECG tracings assessed by the PI or investigator for CS/NCS status and are signed/dated and copies of all tracings made for preservation				
All protocol deviations, violations, and unanticipated problems reviewed and assessed by the PI, noted and reported as required by the study sponsor and per IRB reporting requirements				
IP accountability logs are accurate and complete (if not managed by IDS Pharmacy).				
AEs (including SAEs) appropriately documented and reported on logs				
Paper and electronic forms adhere to GCP standards for good documentation practices (ALCOA+C)				
Data captured in EDC accurately reflects data on CRFs				
Study tasks were performed by staff who were appropriately delegated on the delegation log				
Notes to file and sponsor correspondence specific to subject available				
If complete, the subject's final status is documented				
Other findings:				
Other findings:				