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Standard Operating Procedure
Safety Monitoring

Purpose:

This SOP details the safety monitoring (excluding investigational devices)

Procedure:

Data Safety Monitoring Plan

1. Develop an individual stopping criteria checklist based on the IRB approved protocol.
2. Review and operationalize the data safety and monitoring plan established
3. If there is a safety officer (SO) or DSMB, establish an appropriate charter using the charter template and ensure that the charter has been approved by the SO or DSMB prior to study commencement.
4. Ensure that all data to be reported to the oversight body will be consistently collected and identify a standardized cut-off date for collating the data .
5. If safety reporting is based on the number of subjects enrolled, add a trigger to the enrollment and/or accrual log to identify when the number has been reached.
6. Copies of all monitoring reports must be submitted to the IRB for review.
7. A full copy of the IRB submission sent to the IRB will be placed in the regulatory binder.
8. A member of the research team will note this IRB submission on the IRB submission log, stored in the front of the regulatory binder for this study.
9. Upon receipt of the approval certificate from the IRB, the coordinator will:
    a. Place a copy of the IRB approval certificate in the regulatory binder.
    b. If changes were requested by the IRB as a consequence of their review of the report, submit an amendment in accordance with the Amendment SOP.
10. If the PI is providing oversight then establish how frequently the evaluation will occur.

Unanticipated problem reporting

1. Add copy of applicable IRB reporting policy to regulatory binder
2. Modify the Unanticipated Problem Reporting Log to reflect current policy
3. Train the research team to the current UAP policy and document in the training log
4. Develop a communication plan for reporting issues to the team particularly when a determination of a UAP is required. A UAP must be reported to COMIRB within 5 days
5. The PI should review the UAP log at each research review meeting to ensure that events have been categorized correctly
6. If an event is thought to be reportable as a UAP, then a member of the research team must submit a UAP report to the IRB in accordance with IRB policy within 5 days
7. The submission process to the IRB should be documented using the process outlined for safety monitoring reports above
8. If the investigator determines that the study should be put on voluntary hold until the UAP has been thoroughly investigated and reviewed by the IRB, this information needs to be promptly reported to the study team and documented in the regulatory binder

Adverse event documentation and reporting

9. Identify reporting requirements to the lead site or sponsor or PI
10. Document which resources will be used to determine if an adverse event is expected or unexpected
11. Establish how adverse events will be graded
12. Add adverse event assessment to each study visit data collection sheet
13. Adverse event information should be transferred to the unanticipated problem log within 24 hours and evaluated to determine if it meets the definition of a UAP
14. A summary of adverse events must be reported to the IRB as part of the continuing review
15. A member of the research team should document the data cut-off date on the UAP log, collate the AEs and document that the PI has reviewed the summary prior to submission to the IRB

Deviation documentation and reporting

16. Deviations from the approved study protocol should be documented on the study visit collection sheet
17. Information should be transferred to the deviation log within 24 hours and evaluated to determine if it meets the definition of a UAP or if an amendment is required to avoid future deviations
18. A summary of deviations must be reported to the IRB as part of the continuing review
19. A member of the research team should document the data cut-off date on the Deviation log, collate the deviations and document that the PI has reviewed the summary prior to submission to the IRB

Process for unblinding (if applicable)

1. Establish and document on the delegation log who is responsible for the randomization
2. Document where the blinding code is kept and who has access to the code
3. PI and lead site (if applicable) must concur that unblinding is necessary prior to initiation
4. Document on the UAP log, why the unblinding occurred and follow the reporting policy above for UAPs

Forms:
AE / UAP log
Deviation log

APPLICABLE REGULATIONS AND GUIDELINES

FDA regulations for investigational drugs	21 CFR 312.32
OHRP Human Subjects Regulations	45 CFR 46.103.5 Investigator Responsibilities FAQs http://answers.hhs.gov/ohrp/categories/1567
COMIRB Policy	Section 19 – Unanticipated Problems Involving Risks to Subject or Others and Adverse Events Section 25 - Investigator Responsibilities Investigator Responsibilities Policy Guidance on the Responsibilities for Investigators-Sponsor Conflict of Interest