**OBJECTIVE**

To define the purpose and function of the PAM working group.

**RESPONSIBILITY**

The PAM working group membership consists of:

* Research Compliance Monitors
* School of Medicine Clinical Trials Office Educator and Director
* Senior Associate VP for Research

The Research Compliance Monitors and the SOM CTO Educator will be responsible for creating the reports that are submitted to the group for review.

**PROCEDURE:**

1. The PAM working group will meet on the second Wednesday of each month to review all PAM and education reports conducted the previous month. The PAM reports will be submitted to the group by the Research Compliance Monitors. The education reports will be submitted by the SOM CTO Educator.
2. The group will review each report considering the following:
	* Additional recommendations and/or educational needs.
	* Findings that the full IRB committee should address.
	* Trends or findings with service centers or departments (CRU, Cancer Center, Pharmacy, etc.)
	* Suggestions for policy and or procedural changes as needed.
3. Any IRB-HSR questions or concerns that are identified or any protocols with serious compliance issues will be submitted by the PAM working group to the IRB-HSR PAM Advisory Committee.
4. The PAM working group will assign a criticality score to the findings utilizing the following rating scale:
* Exceptional (Category 1): Regulatory documents complete, evidence of consistent protocol compliance and source documentation. Evidence of research understanding and compliance.
* Satisfactory (Category 1-2): Few minor deviations noted or major deviation with evidence corrective actions are in place and overall assessment of study conduct is good. Education may be recommended.
* Marginal (Category 2): Needs follow-up. At least one major deviation noted or many minor. Education may be required. Re-review will occur in 3-6 months, as determined by the PAM working group.
* Unacceptable (Category 2-3): Extremely deficient review, or after education and re-review, non-compliance is still evident or the degree of subject risk is uncertain.

The ratings will be used for internal reporting to the IRB-HSR and for statistical reporting only.

Any studies deemed unacceptable by the PAM working group will fall back into category 3.

**REFERENCES:** none