**OBJECTIVE**

To define the purpose and function of the IRB PAM Advisory Committee.

**RESPONSIBILITY**

The IRB PAM Advisory Committee membership may consist of:

* Research Compliance Monitors (2)
* IRB Chair
* IRB Vice-Chair
* IRB Director and IRB Compliance Coordinator
* IRB member(s) non-scientist/unaffiliated (community member)
* IRB member Study Coordinator

Note: the composition of the committee and required members for attendance at the meetings may vary. If possible, the meeting attendance will consist of (at least): 1 Research Compliance Monitor, IRB Chair or Vice-Chair, IRB Director or IRB Compliance Coordinator, IRB community member or IRB member Study Coordinator.

**PROCEDURE:**

1. The IRB PAM Advisory Committee will meet on the 4th Tuesday of every month following the IRB-HSR #1 meeting. Alternate meeting times for the committee may be scheduled if most of the members are able to attend the revised date. The committee will review all PAM and education reports conducted the previous month, as well as the minutes from the applicable PAM Working Group meeting.

The Research Compliance Monitors will be responsible for creating the reports and meeting agenda submitted to the committee for review.

1. The committee will review each report considering the following:
	* Additional recommendations and/or educational needs.
	* Findings that the full IRB-HSR board may need to review.
2. The committee will consider the rating assigned for each study PAM report at the PAM Working Group meeting (criteria used for ratings below):
* Exceptional: Regulatory documents complete, evidence of consistent protocol compliance and source documentation. Evidence of research understanding and compliance.
* Satisfactory: 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: Needs follow-up. At least one major deviation noted or many minor. Education may be required. Re-review may occur in 3-6 months or as needed.
* Unacceptable: Extremely deficient review, or after education and re-review, non-compliance is still evident or the degree of subject risk is uncertain.

The committee will confirm the ratings assigned by the PAM Working Group if they agree, or may change the rating if needed. The IRB PAM Advisory Committee will make the final determination of a study PAM report rating.

**REFERENCES: 1-8 Function of the PAM Working Group**