**Section 995.150 Post-Grant Monitoring and Compliance**

a) The Department will monitor all grants awarded.

b) Grantees shall submit written reports of progress toward achieving objectives at:

1) Six months into the grant agreement period;

2) One year into the grant agreement period; and

3) Within a month after the conclusion of the project period.

c) The reports shall include the following:

1) A description of the current status of the project in accordance with the proposed time frames in the application;

2) Documentation on the progress in meeting each project objective in accordance with the proposed time frames in the application;

3) Rationale for any revisions in the evaluation methods or the monitoring plan;

4) A comparison of actual expenses to the budget projections and time frames in the application;

5) A projection of methods and time frames involved to accomplish the pending objectives within the time frame remaining (except for the end of the project summary report);

6) A summary at the close of the project period of the achievements and ultimate conclusions derived as a result of the project; and

7) A description of the grantee's compliance with *current best practices with respect to medical ethics* set forth in Section 995.90 including *informed consent of patients and the protection of human subjects*. (Section 15(c)(5) of the Act)

d) The Department and one or more members of the Panel will review reports submitted by grantees.

e) Grantees shall be subject to periodic on-site inspections by IRMI representatives.

f) IRMI may request an oral presentation to clarify the status or the end of project report for the benefit of the peer review panel or other formally recognized audiences.

g) Grantees shall establish and maintain the necessary processes to monitor their compliance and that of their employees and contractors; take appropriate action to meet the stated objectives; and inform IRMI of any problems or concerns.

h) Grantees are responsible for the actions of their employees and other research collaborators, including third parties involved in the project.