**Section 1580.70 Reporting Requirements**

a) Researchers must report proposed research changes to the IRB and the executive director of the Authority. The executive director of the Authority shall inform the appropriate funding agency.

b) Any unanticipated problems involving risk or harm to subjects or others, noncompliance with applicable laws or regulations, or IRB requirements or determinations, must be immediately reported by the researcher to the IRB and the executive director of the Authority. The Authority and the IRB shall have the authorization and duty to suspend or terminate approval of research that is not being conducted in accordance with applicable laws or regulations, or IRB requirements or determinations, or that has been associated with unexpected risks or harm to subjects or others. Any suspension or termination of approval by the Authority or the IRB shall include a statement of the reasons for that action.

c) The executive director of the Authority shall notify the appropriate funding agency of any unanticipated problems involving risk or harm to subjects or others, any instance of serious or continuing noncompliance with applicable laws or regulations, or IRB requirements or determinations, and all suspensions and terminations of research approval.

d) The executive director of the Authority will forward all required certifications and documentation regarding the IRB review to the appropriate funding agency.

e) The researchers may be required to submit progress reports to the IRB, the nature and frequency of which will be specified by the IRB.

f) The IRB shall submit a report to the Authority's Planning and Research Committee on the actions of the IRB, prior to the committee's regular meetings.