If the IRB decides to suspend or terminate its approval of a research project, the IRB will ascertain whether there are subjects enrolled in the research. If there are currently enrolled subjects, the IRB will work with the PI to ensure that a plan is in place to appropriately notify subjects and that procedures for subject withdrawal consider the rights and welfare of those subjects. IRB decisions for suspension or termination of approval will be reported to the IO.

G. Reporting Requirements

In the event that serious or continuing non-compliance is identified, the Director, ORIC will work with the RIO/IO to report the non-compliance to external regulatory agencies, in accordance with applicable federal, state, and local laws. Once a reportable event has been identified and the letter has been drafted, they will consult with the Corporate Compliance Office and/or the Office of General Counsel for review. The report is to be filed promptly (i.e., typically within 30 days of recognition of the reportable event). The final report and related documents are filed and maintained by the ORIC office.

External entities include, but are not limited to:

- Office for Human Research Protections (OHRP) - if the study is subject to U.S. Department of Health and Human Services (DHHS) regulations;
- Other federal agencies when the research is subject to those agencies and the agency requires reporting separate from that to OHRP (e.g. Department of Defense components, etc.);
- Food and Drug Administration (FDA) - when the research is FDA-regulated;
- Sponsors of the research - as appropriate; and/or
- Funding source of the research - as appropriate.

14.2 INSPECTIONS BY REGULATORY AGENCIES

Certain regulatory authorities, funding and accrediting agencies have the authority to inspect study records and the operations of the IRB. It is the expectation of the Institution that investigators and research staff, ORIC, and the IRB will cooperate with inspections conducted by external agencies in compliance with these regulations. The PI or designee should notify ORIC when an external audit is expected. ORIC will notify additional entities within the Institution as appropriate and will provide support preparing for and during the audit.

Reports of external inspections of research records are to be submitted to ORIC. The Director, ORIC, in consultation with the additional Institutional entities (e.g. IO, IRB Chair, General Counsel, Corporate Compliance, Privacy Officer, etc.) will assist the PI in addressing any findings and responding to the regulatory agency.

Copies of external inspection reports are to be maintained by the PI and/or ORIC according to the IRB Record Retention Policy.