The Institutional Review Boards shall:

1. Review, approve, require modifications to, or disapprove research studies involving human subjects.

2. Monitor approved research studies on a regular basis for compliance with federal, state, and local regulations and university policies, including the consent process.

3. Monitor, and may act in response to, unanticipated problems and adverse events.

4. Require the submission of renewal applications from investigators on at least an annual basis or more frequently depending on the degree of risk with limited exceptions provided in the Human Research Protection Program Manual 8-8 “Demonstration Projects.”

5. Comply fully with the requirements of 45 CFR 46, 21 CFR 50 and 56, the Federal Wide Assurance (FWA) and the terms of the assurance, all federal, state and local laws, and university requirements.

6. Arrange for prompt reporting, in conjunction with the university, pursuant to HRPP Manual 4-8 “Reporting” of any:
   a. Unanticipated problems involving risks to subjects or others:
   b. Serious or continuing noncompliance; and
   c. Suspension or termination of IRB approval.

7. Maintain an operating manual and other written material describing its human research protection program appropriate for the volume and nature of the research involving human participants conducted under its auspices.

8. Maintain and support a current and approved FWA and IRB registration.

9. Maintain and implement written policies and procedures for addressing serious and unanticipated risks to research participants or others.

10. Maintain and implement written policies and procedures for addressing allegations and findings of non-compliance with IRB requirements.