

HARVARD PILGRIM HEALTH CARE QUALITY ASSURANCE AND QUALITY IMPROVEMENT (QA/QI) FREQUENTLY ASKED QUESTIONS

I. What QA/QI functions are performed at HPHC/I?

Some of these QA/QI functions performed by the research integrity & compliance staff include:

1. Assessing the functioning of the IRB and its compliance with regulations and policy;
2. Identifying areas where investigators, IRB members and staff can benefit from training activities and preparing educational materials that are targeted to the needs of the research community; and
3. Reviewing current guidelines from OHRP, ORI or other regulatory agencies for issues involving human subjects' research.

II. What are some examples of the types of QA/QI work performed?

1. Review of IRB meeting minutes to ensure they contained the information required by law;
2. Review of various policies, procedures and forms for compliance with applicable laws;
3. Review of the IRB roster for compliance with applicable law and accreditation standards; and
4. Review of study files.