Office for Human Research Protections (OHRP)
Division of Assurances and Quality Improvement

Objectives and Overview of the OHRP Quality Improvement Program
April 15, 2002

The Office for Human Research Protections (OHRP) is pleased to announce that it is launching a Quality Improvement (QI) Program intended to help institutions evaluate and improve the quality of their human research protection program. The program was made available to institutions and institutional review boards (IRBs) on a voluntary basis starting January 2002.

Background

OHRP recognizes that institutions and their human research protection programs face enormous challenges with the administration, review, and conduct of human subjects research. These challenges include ensuring that research activities are conducted not only in a manner that complies with federal regulations for the protection of human subjects, but also meets ever evolving ethical standards related to advances in technology, science, and changing cultural values and societal issues.

Over the past several years, institutions and IRBs have faced increasing scrutiny and/or criticism from the public, media, and the federal government's Office of the Inspector General (OIG) and the General Accounting Office (GAO). Such criticism includes the failure to: 1) obtain prospective IRB approval, 2) minimize risks for subjects, 3) obtain legally effective informed consent, 4) provide oversight or adequate continuing review of human subjects research, and
5) eliminate or minimize conflicts of interest. Upon investigating allegations of noncompliance at institutions, the OHRP Division of Compliance Oversight has too frequently discovered serious systemic deficiencies in human subjects protection programs. As a result of the increased public and governmental scrutiny of human subjects research and the discovery of incidents of noncompliance with federal regulations and ethical standards, some of which have resulted in harms to human subjects, public trust in our nation's human research enterprise is threatened.

The Department of Health and Human Services (DHHS) believes that we must move from a reactive, compliance-focused system of oversight and sanctions to a new model, one that is not only proactive, but interactive, and emphasizes prevention of harm. Toward this end, OHRP plans to work together with all components of the human research community (e.g., subjects, institutions, IRBs, investigators, sponsors, and the public) to strengthen our national human research protection system. To strengthen individual institutional human subjects protection programs, the OHRP Division of Assurances and Quality Improvement (DAQI) has developed a new QI Program to offer consultation and support. The QI Program is intended to benefit human subjects protection programs at institutions that conduct biomedical, social, or behavioral research, as well as independent IRBs.

Objectives

The primary purpose of the QI Program is to increase the quality, performance, and efficiency of an institution's human subjects protection program. Secondarily, the QI Program is designed to help institutions ensure compliance with federal regulations for the protection of human subjects in research. OHRP further intends this program to help institutions prepare to achieve accreditation of their human research protection programs by private-sector accrediting entities. DHHS believes that such accreditation is an important complementary process for strengthening and improving the performance of the national system for protection of human subjects in research.

Description of the QI Program

The program will include three components or stages: 1) Quality Assurance, 2) Quality Improvement, and 3) Continuous Quality Improvement. Through the QI Program, DAQI offers assessment, instruction, education, and sharing of best practices.

1) Quality Assurance (QA)

The first component will provide activities intended to promote a solid foundation for a human subjects protection program. Before a program can be improved, one needs to provide an assessment of the program's strengths and weaknesses. During this stage, DAQI will guide institutions in conducting a self assessment. To facilitate this process, DAQI has developed a self-assessment tool that can be utilized by institutions and independent IRBs. The self-assessment tool is primarily intended to gauge an institution's compliance with the federal regulations for human subjects protection. Additionally, a review of the human subjects protection program's operating procedures by DAQI may occur during this stage. DAQI will then evaluate the assessment and interact with the institution via any of three modes of communication: 1) written correspondence and teleconference, 2) videoconference, and 3) on-site consultation visit. Selection of the type of interaction will be made by DAQI based on the need and willingness of the institution, the overall demand and volume of requests received, and resources available at DAQI.

After evaluation by DAQI, the institution will be provided with appropriate guidance and recommendations for improving its system for protecting human subjects. Education and consultation will be offered by DAQI staff to improve the human subjects protection program in any necessary area(s). The interactions between DAQI and an institution will be conducted in a collegial manner, and the process will include mechanisms to protect the confidentiality of information voluntarily provided by the institution.

2) Quality Improvement (QI)

QI will be offered by various means. First of all, having previously conducted QA, a certain level of improvement can begin from the increased awareness of existing processes and the evaluation of operating procedures. Identifying an institution's strengths and weaknesses is essential in any improvement process. Compliance with the federal regulations for the protection of human subjects inherently provides a certain level of quality. However, compliance with these regulations does not necessarily mean that human research will be reviewed or conducted with a high degree of quality. Therefore, the QI process will focus on mechanisms by which a human subjects protection program can improve its functions.

Initially, DAQI will offer consultation on how improvement can be enhanced. Best practices, procedures, and tools that can increase quality and performance will be posted on the OHRP website. When DAQI finds a best practice at a given institution, it will be posted anonymously on the OHRP website if permission is granted by the institution. Additionally, DAQI will foster networking relationships for the sharing of best practices between institutions in need of guidance and institutions willing to provide guidance. Again, the brokering of networking relationships will occur only after permission is granted by the institutions for a specific interaction. With these approaches, the nation's IRB infrastructure will be improved with the input of many individuals in the IRB community. In the future, DAQI will work to develop products or tools that may further enhance QI.

3) Continuous Quality Improvement (CQI)

In the third component, CQI, DAQI will provide guidance for the development of an institution's own QA/QI process on a continuous basis. The ultimate goals are to have human subjects protection programs perform at a high level of quality and to assist institutions and independent IRBs in the creation of their own QI programs. Again, on a voluntary basis, DAQI plans to share strategies and information for CQI. DAQI plans to implement this last stage in mid to late 2002.

Confidentiality

Since the OHRP QI Program is a voluntary program, information collected under this Program may be determined exempt from the requirements of the Freedom of Information Act (FOIA), pursuant to Exemption 4. Exemption 4 permits the withholding of trade secrets and information that is submitted, on a voluntary basis, to the QI Program that are commercial, financial, confidential, or privileged. Prior to submission of any records, an institution can identify those records, or portions thereof, that it believes are within the scope of Exemption 4. If requested under FOIA, OHRP FOIA officials will review the information to determine the applicability of the exemption. If designated information is required to be released, institutions will be notified prior to such release.

DAQI is sensitive to the potential confidentiality concerns an institution may have with regard to discovery of noncompliance. DAQI will not ordinarily communicate its observations during the QI activity to the OHRP Division of Compliance Oversight (DCO). In the unlikely event that serious systemic noncompliance or a serious problem(s) that had resulted in or may pose a threat to the safety and well-being of research subjects is discovered during a QI consultation, institutional officials will be appropriately notified and will be expected to take immediate action to remedy the situation, including filing an appropriate corrective action plan with OHRP. In such a case, OHRP will work intensively with the institution to develop and implement a corrective action plan in a timely and collegial manner.

Initiation of Process

Pilot testing of the OHRP QI Program began in July 2001 and pilot testing of the first component, QA, was concluded in November 2001. Institutions and independent IRBs interested on a voluntary basis in initiating the self-assessment process may submit a request in writing to DAQI. Questions and correspondence regarding the QI Program should be directed to:

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