



Office for Human Research Protections
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An Open Letter to the Human Research Community

*From Greg Koski, Ph.D., M.D.
Director, Office for Human Research Protections
Department of Health and Human Services*

Dear Friends and Colleagues:

Last spring I wrote to you about the implementation of the first phase of the Office for Human Research Protection's new quality improvement (QI) program. At that time I invited institutions to join us in our QI activities, aimed at enhancing the effectiveness of our nation's protection system for human research participants. Within hours of that invitation, you began contacting our office to schedule QI consultations. We appreciate the participation of all who volunteered to be among the trailblazers in this initiative and would like to encourage all other research institutions to take part in this initiative.

At the same time we also recognize the need for greater accountability throughout our system. Both our QI program and our compliance oversight responsibilities work effectively together to strengthen OHRP's mission. As an enhancement to current activities, we are announcing the expansion of our not-for-cause surveillance evaluations (NFC evaluations) by the Division of Compliance Oversight. These NFC evaluations are separate from 'for-cause investigations' that our office traditionally initiates in response to complaints and distinct from the QI consultations conducted by the Division of Assurances and Quality Improvement.

Institutions will be selected for NFC evaluations according to criteria that will ensure that a representative sampling of institutions is included on a regular basis, and that OHRP's resources are used effectively and efficiently. Our NFC evaluations will begin with an examination of institutional review board documentation, policies and procedures. This will be followed by additional interactions that may also include exchanges of information by correspondence, telephone, or videoconference. Occasionally, a site visit may be the most appropriate means of carrying out the NFC evaluation.

To help reduce the administrative burdens on all parties, we will make every reasonable effort to avoid redundancies between the NFC evaluation and the QI programs. When an institution is selected for an NFC evaluation, OHRP will defer that evaluation if the institution satisfies one of the following two criteria:

- the institution has participated in the QI program within the past 24 months, or
- the institution has already contacted OHRP in writing to request a QI consultation and is proceeding with the QI consultation in the time frame mutually agreed upon with OHRP.

If the institution is unable to complete the necessary work for a QI consultation within the specified time frame, then the institution will be placed back in the pool for a potential NFC evaluation.

In any given time period, OHRP would expect to provide about eight QI consultations for every one NFC evaluation that it carries out. We believe that this 8:1 ratio of effort will optimize the effectiveness of both the QI consultations and the NFC evaluations.

Your participation in both these initiatives underscores your continuing commitment to a productive and responsible research environment. OHRP continues to believe that we can “*Do It Right Together.*” The staff joins me in thanking you for your continued support, cooperation and commitment to the protection of all research volunteers.

You can learn more about the program from our website at <http://ohrp.osophs.dhhs.gov>, or volunteer by sending an e-mail to QI@osophs.dhhs.gov.

Sincerely,

Greg Koski