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**Office for Human Research Protections  
The Tower Building  
1101 Wootton Parkway, Suite 200  
Rockville, Maryland 20852  
Telephone: 301-496-7005  
FAX: 301-402-0527**

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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*

To Those We Serve:

It is hard to believe that only a year and a half ago, we were only laying out a blueprint for remodeling our national system for protection of human subjects in research. One can easily lose track of time, particularly in Washington, where some things never stay the same, and others never seem to change. Recently, preparations for an upcoming Senate hearing on human subjects protections afforded an opportunity for me to reflect on all that has happened over these past 18 months, all of which have been challenging.

No one will deny that human research is in the midst of a dramatic period of change, a period that brings with it anxiety and frustration as well as hope. Anyone who has lived through the remodeling of a kitchen knows how disruptive the process of change can be, but the results are well worth the wait and the inconvenience.

A key element of the remodeling process in human research protections is the move from a system focused on regulatory compliance to a system focused on prevention of harm. Many times over the past year and a half we have heard the sound bites and catch phrases—"shared goals and shared responsibilities," "flexibility with accountability," "do it right because it's the right thing to do." For all of us in OHRP, these are more than words...they are our mantra and our mission.

We are now at a critical juncture in the transition to our new system. OHRP has worked long and hard with many of you to develop a new quality improvement program, one that offers support and consultation, one that seeks collaboration, not confrontation. The program was announced at the December meeting of Public Responsibility in Medicine and Research, and a more formal announcement was posted on our website a few weeks ago. Now, we are ready to go, and it is your turn to take the initiative.

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While we await final approval of our directed self-assessment tool, we will begin scheduling quality improvement (QI) consultations for the next 6 months as we build out this program to its full capacity of 60 consultations per month. All of the consultations involve a self-evaluation of a program by its staff, with follow-up from the staff of our Division of Assurances and Quality Improvement. Some follow-up may be through calls or correspondence. Others may involve videoconferences or on-site consultation visits. All of them will be collegial and constructive. Our highest priority will be those institutions that receive the greatest federal support for research. I am hoping that institutions will choose to volunteer to participate in this program now.

Why now? What is so important about today? Why not wait until next year? Why should we be first? The answer is simple and clear. This program, upon which the successful transformation of our oversight system depends, cannot proceed unless those institutions engaged in human research take the initiative to volunteer to participate.

Is there an alternative? Yes, of course there is. There are many who remain skeptical that a system focused on prevention and quality improvement can be effective. These are often the same critics who believe that only through stronger oversight and enforcement activities can meaningful change result. OHRP wants to prove them wrong.

Clearly, there is a necessary and appropriate role for oversight and enforcement, even penalties in egregious cases, but I believe that the vast preponderance of scientists, IRB members, and institutions are well intentioned. I have seen first hand in my visits to institutions across the country the remarkable efforts that are being made to strengthen programs, educate individuals, and ensure the well-being of research participants. Participation in OHRP's new Quality Improvement Program is a critical first step in building confidence and trust in the human subjects protection process, to show that we can "do it right, together."

In "Field of Dreams" they said, "If you build it, they will come." Now is the time for action. I urge you to take it. 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](mailto:QI@osophs.dhhs.gov). Please contact us today to set a time for your consultation.

Sincerely,

Greg Koski