



Assessment

TO: Members of the University Community

FROM: Michael B. Breton, Ph. D.
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RE: Announcement of the Human Subjects Assessment Initiative

Protecting the people who participate in the many human subjects research activities at Rutgers is of the utmost importance to researchers and the University. The Office of Research and Sponsored Programs (ORSP), in conjunction with the Institutional Review Board for the Protection of Human Subjects (IRB), wishes to expand their collaboration with researchers to help ensure this end by establishing the Assessment Initiative. As part of the IRB Quality Assurance Program, the Assessment Initiative, is meant to serve as an educational as well as an assessment tool for both researchers and administrators and will give researchers an opportunity to review their on-going protocols. During the process, administrators will learn first hand of the concerns researchers encounter when conducting human subjects research, and take them into account as policies and procedures are refined and developed. Through an open dialogue regarding the federal requirements, researchers will continue to improve their understanding of the expectations for human subjects research. It will improve the human subjects program at Rutgers for researchers, administration and most importantly, the people who participate in the research. It is only by working together that we can achieve this important goal.

The Assessment Initiative helps fulfill Rutgers' obligation to self-monitor the human subjects program in accord with our Federalwide Assurance agreement with the Office for Human Research

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Protections (OHRP). This type of program has quickly become the norm throughout the nation, and as an AAU institution, Rutgers must achieve this standard. Your cooperation in this joint venture is much appreciated.

Both ORSP and the IRB understand how valuable your time is and certainly do not wish to make this federal mandate burdensome. It was with this understanding that the Assessment Initiative has been designed to be user-friendly, concise and rely in large part, on the cooperation and participation of the researchers. It is essential to note that there are two key elements of the program:

Self-assessment. All investigators will participate in this aspect.

Face-to-face assessment. A small percentage of investigators will be selected to participate in this aspect.

An overview of the Assessment Initiative is as follows:

1. All researchers will **immediately** begin conducting the self-assessment portion for each of their non-exempt protocols. The first step is to organize the protocol related documents. *Documentation for the Human Subjects Assurance Initiative* describes the information that is necessary for researchers to organize. It can be found on-line at: <<http://orsp.rutgers.edu/humans/assessmentdoc.php>>.
2. Researchers will also complete a Self-Assessment Checklist. The easy to use form can be found on-line at <https://www.rci.rutgers.edu/~orsp/selfassess/selfassess.php>. This checklist was refined as the result of a pilot project conducted with IRB members and Liaisons to the IRB.
3. While all investigators will be conducting self-assessments, protocols in which participation has been determined to be at greater than minimal risk by the IRB will be given priority for participating in the **face-to-face assessment**. In most cases the selection will be done at random. Only a small percentage of the many protocols will undergo this process. The face-to-face assessment visitations will begin in early June.
4. It is important to again emphasize that all investigators should begin the process with their research teams now.

In anticipation of questions about this program, *Commonly Asked Questions and Answers Regarding the Human Subjects Assessment Initiative* was written. It can be found on-line at <<http://orsp.rutgers.edu/humans/assessmentqa.php>>.

Our office welcomes any questions. Please direct them to either James Cavazzoni, Sponsored

Programs Administrator, at cavazzoni@orsp.rutgers.edu or 732-932-0150 ext. 2104; or to Karen Janes, Associate Director of Research Integrity and Compliance at janes@orsp.rutgers.edu or 732-932-0150 ext. 2105.

Congress has declared that conducting research is a privilege, not a right. We should be very proud of the Human Subjects Research conducted at Rutgers and must protect that privilege of doing research for all investigators at Rutgers. Many of you are aware that over recent years, the (OHRP), Department of Health and Human Services, has stopped *all* human subjects work at several institutions. We would never want that to occur at Rutgers. Both the Research Integrity and Compliance unit of ORSP and the IRB look forward to working together with you in continuing to create a strong program of human subjects protection at Rutgers University. Thank you for your cooperation. We could not fulfill this federal requirement without your full participation.

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