An Institutional Review Board (IRB) is a committee designated by an institution to help assure the protection of the rights and welfare of human subjects. The IRB approves the initiation of and conducts periodic reviews of research involving human subjects. Investigators also share the responsibility for protecting human subjects.

**Reminder Notice Regarding Continuing Reviews of Research**

This is a reminder that the IRB does not permit extensions of research projects beyond the IRB approval dates. Federal guidelines and University policy require that continuing review of nonexempt research be conducted by the IRB at intervals appropriate to the degree of risk and not less than once per year. The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. The renewal application form is posted on the ORAA website at http://www.umresearch.umd.edu/ORAA/forms/umoraa.html#6. The IRB Office sends reminder notifications to Principal Investigators at least 30 days prior to the expiration date of IRB approval. If it is in the best interest of individual subjects to continue participating in interventions or interactions for research in which approval has recently expired, the Principal Investigator should submit a request, to the IRB, for those research subjects to continue participating. The request should include a description of the potential harm if the subjects do not continue participating in the research. If you have any questions regarding this notice, please contact Roslyn Edson, IRB Manager at 301-405-0678 or redson@umresearch.umd.edu

**Changes to IRB Policies, Procedures and Guidance**

Some of the IRB policies, procedures and guidance recently changed including the IRB application process, the consent form guidance documents, the IRB review procedures, and the IRB website. These changes were made to help ensure compliance with the Federal regulations and guidance for the protection of human subjects and simplify the IRB review process. The changes to the IRB policies, procedures and guidance are described below.

**IRB Application Process**

On April 20, 2005, the two IRB initial application forms were replaced with one IRB Initial Application Form (MS Word doc). Previously, the Departmental Application Form was used if the research involved no more than minimal risk AND the department had a Human Subjects Review Committee (HSRC) and the IRB Initial Application form was used if the research involved more than minimal risk OR the department did not have a
Human Subjects Review Committee. These two forms are no longer available on the IRB website and have been replaced with one IRB initial application form (MS Word doc). The new form requires the signature of the Principal Investigator, Co-Principal Investigator (if applicable), Student Investigator (if applicable) and the Departmental representative. The departmental signature block should be signed by the IRB Liaison for those Departments with IRB Liaisons. Please refer to the listing of IRB Liaisons (IRB Liaison Roster). If an IRB Liaison is not listed for your Department, please contact your Department to find out who should sign the IRB application. Applications must now include additional information for research conducted outside of the United States and research involving prisoners. If the sections are not applicable, the application should state "Not Applicable" or "N/A" for each of these sections. Another major change is that additional information is required for research involving audiotapes, videotapes and digital recordings. The additional information that is required for the initial and renewal applications is described in the application instructions (MS Word doc).

Consent Form Guidance Documents

On April 20, 2005, the sample consent form was revised and additional consent form guidance documents were added to the website. These additional guidance documents include: a consent form template and an appendix with additional guidance for specific issues such as research involving minors and research involving audio taping, videotaping, digital recordings or photographs. The consent form guidance documents are attached to the IRB Initial Application Form (MS Word doc) and Renewal Application Form (MS Word doc). These guidance documents replace previous versions of the sample consent form and the Guide for Reviewing Human Subjects Research Consent Forms which was distributed to the HSRC Chairs in Fall 2004.

Exempt Review Procedures

On February 3, 2005, the IRB Manager began reviewing and approving exempt research. Exempt research is usually reviewed within one week upon receipt (Exemption Categories). Additional guidance is included with the list of exemption categories.

IRB Training

The IRB Manager conducts training sessions for the IRB Liaisons who review and sign IRB applications. These 2-hour training sessions include a discussion of the changes to the Departmental review procedures. The training sessions also cover the exempt, expedited and full Board review procedures and common problems requiring the submission of revised applications and revised consent forms. Others are welcome to attend. Please register in advance.

If you have any questions regarding these recent changes or have any suggestions, please contact us at irb@deans.umd.edu or refer to the IRB staff contact information.