CONTINUING REVIEW REQUIREMENTS

1. CURRENT FORMS

All submissions must be completed on the most current IRB-01 forms. Since forms are often updated, it is strongly recommended that you always download any needed forms from the web before completion and submission. This includes, but is not limited to, the Continuing Review/Study Closure Report, Informed Consent Form, Revision Memo, Adverse Event Table, and any other forms you submit to the IRB. The only exception: revisions to a previously approved Project Cover Sheet, Introductory Questionnaire, or Protocol do not need to be updated to the new format - UNLESS requested by the IRB.

2. COPY OF CURRENT PROTOCOL AND ANY OTHER APPLICABLE FORMS

New in 2007, Investigators are required to submit a clean copy of the current protocol along with any other applicable forms including, but not limited to, a completed Cumulative Adverse Event and Unanticipated Problems Reporting Table, DSMB reports, Audit Reports, publications or meeting proceedings, and/or any other new findings/publications that relate to the risk/benefit ratio of the study. Additionally you must provide a copy of the Informed Consent form signed by the last subject enrolled on your study (even if it is the same as the previous year). Use a black marker to block out any/all references to the subject’s identity, including the name, initials, and medical record number. The only exception: if the IRB has previously approved a waiver or modification of Informed Consent.

3. CLEAN COPY OF INFORMED CONSENT FORM IN CURRENT FORMAT

This is required if the following are true: (1) the IRB has not previously approved a waiver or modification of informed consent, (2) you wish to enroll additional subjects to this study (your project is open to enrollment), and/or (3) you are revising your consent and it may be necessary to re-consent subjects who are already enrolled in the study. A new, clean copy of the Informed Consent Form in the current format is NOT required if (1) you previously obtained a waiver of informed consent, or (2) you are not enrolling any new subjects AND your consent is not being revised.

4. GUIDELINES AND PROCEDURES FOR SUBMITTING RESEARCH TO THE IRB FOR REVIEW

Review these Guidelines at http://irb.ufl.edu/irb01/forms.htm to help ensure that your submission can be forwarded for review upon receipt. Failure to follow the Guidelines could result in a delay in the processing of your paperwork. Examples of items needed include submitting 5 copies of your paperwork, paperwork must be typed on the current forms and signed by the PI, etc.

5. FULL BOARD DEADLINES

The full Board meets on the first and third Wednesdays of every month. If your project needs to be reviewed and approved by the Full Board, you must submit your Continuing Review/Study Closure Report before the deadline for that meeting (typically 23 days prior to the meeting). The deadlines for full Board meetings are available at the link above. Deadline exceptions will only be made if subject safety is at risk or for significant extenuating circumstances.

6. IF YOUR PROJECT EXPIRES

You cannot: (1) collect, use, or report of any data; (2) perform any study interventions, unless the IRB finds that it is in the best interests of individual subjects to continue participating in research interventions or interactions; (3) enroll or screen any new subjects; and/or (4) receive any study funding. If a study expires and enrolled subjects are undergoing study interventions, the PI must contact the IRB (and for VA Research, the VA Chief of Staff) who will determine if it is in the best interest of the subject to continue participation. There is no grace period extending approval for the conduct of research beyond the expiration date. Once a project expires, IRB review and re-approval must occur before re-initiation of research occurs. According to federal regulations you may not conduct research without an effective IRB approval. Subsequent IRB approval does not authorize you to retroactively collect or use any data that occurred during a period without IRB approval.

Once your project expires, you have 30 days from the expiration date to submit the Continuing Review/Study Closure report. Failure to provide this information within 30 days will automatically move your project to Expired-Nonrenewable status. You will need to re-submit your study as a new project if you wish to continue the research or to receive additional funding.

IRB version 04/17/2007