Continuing Review Process

Miami Valley Hospital, Clinical Research Center Weber Center for Health Education 128 E. Apple Street; #6824 Dayton, OH 45409 Phone (937) 208-2238 Fax (937) 208-5075 e-mail rswirth@PremierHealth.com

All continuing review (CR) applications that are active under either the WSU IRB or the MVH IRB will be processed by the Wright State University IRB. All studies that were originally approved by the MVH IRB have either already been transferred to the WSU IRB or will be transferred at the time of the 2013 CR.

The IRB may provide warning notices of study expiration to Principal Investigators prior to the study expiration date, but investigators should understand that these are a courtesy and are not required. It is the responsibility of the Principal Investigator to monitor approval periods and to ensure that CR applications are filed in ample time to allow for IRB review. The IRB office does not send out CR reminders for exempt studies and will close the studies at the end of the two year period.

If IRB approval expires, all research activities must stop. This includes recruitment, advertisement, screening, enrollment, consent, interventions, interactions, collection of private identifiable information and data analysis. Advertisements currently running in the media must be pulled.

Please complete the WSU IRB renewal form on the <u>WSU IRB website</u>. Please note there are separate forms for renewing a study originally approved as a Full Board study, an Expedited study or for closing any study. After completing the application, be sure to save a copy to your computer.

If you are applying to continue the study with <u>continued enrollment</u> please: Type the CR information into the form on your workstation. (*HINT: If you double click on the check boxes you can select the radio button to check or uncheck the box*). Save the form to your network or local drive. Print the form, sign the last page and attach the current Informed Consent document (if applicable). If there have been changes to any surveys, questionnaires or data collection instruments that are used in conjunction with this study, include these in the submission. The original submission should be single-sided documents. There are two options for submitting the CR application:

- OPTION 1: Make the required number of copies and submit your application to the IRB at 201J University hall:
 - <u>If the study is expedited</u> send 10 copies of the documents to the attention of Jodi Blacklidge.
 - o <u>If your study is exempt</u>, send only one copy.
 - If your study is "Full Board" Please download and complete the questionnaire (INCLUDING THE HSP#) and return via e-mail all appropriate documentation to <u>robyn.wilks@wright.edu</u>. For multi-site studies, the information provided should include only that for your site. If the protocol is to be continued with accrual of additional subjects, SEND A COPY OF THE INFORMED CONSENT FORM CURRENTLY IN USE FOR THE PROJECT.
 - If you choose Option 1, please e-mail <u>rswirth@PremierHealth.com</u> and let her know that you submitted the CR directly to the WSU IRB. Include the SC# or HSP#.
- OPTION 2: Send or deliver the documents to the MVH Clinical Research Center (CRC) on the 6th floor of the Weber building at MVH. MVH CRC Staff will make the required number of copies and send them to the WSU IRB. Allow 3 working days for the documents to be copied and delivered by courier to the WSU IRB. The documents must be in the WSU IRB office prior to the deadline to be considered at the subsequent IRB meeting.

If you are **<u>closing the study completely</u>**, you need only submit the completed application for closing a study.

If you do not respond to the questionnaire before the study expires, the IRB will assume that you no longer wish to continue with the activities described in the protocol and it will be inactivated.