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**Subject:**

General Announcement: Study Personnel List Requirement

Everyone,

It is Institutional Review Board (IRB) policy that changes to Study Personnel (SP) are reviewed and approved by the IRB *prior* to research procedures being implemented by the new SP (or in the absence of previously approved SP). Review of the updated list, including **all** SP holding responsibilities with the study, assures the IRB that all those involved have the knowledge, training, and expertise to appropriately obtain informed consent and implement study procedures. If the changes involve removal of SP, IRB review of the **complete** list of individuals remaining as study personnel assures the IRB that appropriate expertise remains with the protocol.

Both the IRB and Office of research Integrity (ORI) appreciate the challenge of maintaining a list of individuals holding responsibilities on a protocol when resources and staff fluctuate. With this understanding, the IRB/ORI is supplementing the above described policy with a requirement aiming to facilitate consistency and accuracy with study personnel lists, and ultimately benefiting PI's/research staff, the IRB, and most importantly, human subject protections.

Beginning March 1, 2008, the ORI/IRB will begin requiring a **complete** list of study personnel to be submitted:

- 1) at Continuation Review (CR) time (regardless of whether a change is being requested) and
- 2) upon submission of a Modification Request (MR) if the request involves a change to study personnel.

The SP list should include designation of responsibilities including who is authorized to obtain informed consent and whether the individual listed has completed the mandatory human research protections training. *To ensure all pertinent information is included, it is strongly recommended that the IRB/ORI Study Personnel List Template [WORD] [RTF] be utilized (alternately, the SP List found at the end of "Form A"/General Information Sheet of the IRB application can also be used as it is the same format).*

Please note, copies of signed consent forms submitted at CR time containing the name of an individual on the "person obtaining consent" signature line who is not authorized to obtain consent, or an individual on the "Investigator" signature line who is not designated as an Investigator according to the current IRB approved study personnel list, may result in a request from the IRB for corrective action. Corrective actions requested by the IRB, aside from updating the study personnel list, could involve re-consenting the subject in order to obtain appropriate signatures, or not allowing the data from that subject to be used.

The IRB/ORI recognize the new requirement may involve more attention at the onset but anticipate efficiency increasing after the initial effort has been expended. To assist you with organizing your records, the IRB recommends use of a Staff Signature Log (samples available: <http://www.research.uky.edu/ori/QIP/QIP%20Main.htm#Logs>). Also, ORI maintains a database which includes a list of IRB-approved study personnel; upon request, ORI staff can provide you with a list of study personnel (please call 859-257-9428 or e-mail [cdmay1@pop.uky.edu](mailto:cdmay1@pop.uky.edu) and provide your name and the IRB #).

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