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To: All UCB Investigators

In the human research community, it is the Lead Investigators and those interacting directly with participants who have the ultimate responsibility to conduct ethical research. The Institutional Review Board (IRB) and its staff also play a vital role in this endeavor by knowing and applying human subject regulations and guidelines, assisting and educating investigators, and helping to protect the rights and welfare of participants in human research at all times. Having current, written procedures for carrying out these responsibilities is important to this process.

The following materials reflect the most recent Policies and Procedures (P&P) of the University of California at Berkeley's IRB, the Committee for Protection of Human Subjects (CPHS), and staff of the Office for the Protection of Human Subjects (OPHS). These policies and procedures are followed in approving, recommending modifications, and in extremely rare cases, suspending or terminating research involving human subjects.

UC Berkeley operates within the regulations and guidelines set forth by federal authorities, primarily the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), and other bodies such as the International Conference of Harmonisation, all based upon ethical principles elucidated in the Belmont Report. Many of the policies and procedures are derived from these regulations.

As with any road map, it is unlikely that one individual will need all the information gathered in these P&Ps, but they are intended to be easily navigated to find what is needed.

I am grateful to OPHS Director Dr. Rebecca Armstrong and her staff for their meticulous work in preparing these documents. If you have any questions or suggestions, please feel free to contact me.

A handwritten signature in black ink, appearing to read "M Potts".

Malcolm Potts, M.B., BChir, Ph.D.
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