

Icahn School of Medicine at Mount Sinai Mount Sinai Beth Israel Mount Sinai Brooklyn The Mount Sinai Hospital Mount Sinai Queens New York Eye and Ear Infirmary of Mount Sinai Mount Sinai St. Luke's Mount Sinai West **Program for the Protection of Human Subjects** *Institutional Review Boards*

Mount Sinai Health System One Gustave L. Levy Place, Box 1081 New York, NY 10029-6574 T 212-824-8200 F 212-876-6789 irb@mssm.edu icahn.mssm.edu/pphs

Certificates of Confidentiality (CoC) - NIH Policy Change effective 10/1/17

As of 10/1/17, the National Institutes of Health (NIH) has radically changed its policy regarding issuing CoCs. This policy effects any research involving human subjects, their information or samples or projects that generate genomic information.

This requires the attention of the Investigator and impacted research subjects must be notified. Projects that already have a CoC are not impacted by this change. Projects that are not funded by the NIH are not impacted by this change and the process for obtaining a CoC is unchanged.

It is the responsibility of the PI to implement a mechanism to notify impacted research subjects who have already consented for involved research. Letter, emails and phone calls can be used. In person notification is also acceptable.

Please complete the Investigator's CoC Notification Plan and return to the PPHS at IRB@mssm.edu. The PPHS will not be sending out routine acknowledgements of receipt. We will contact you if we have any questions. If a receipt is required please contact the PPHS with your request and justification.

For those choosing to notify in writing, the research team will be responsible for preparing the "stuffed" addressed envelopes. The mailroom has graciously agreed to do mailing of up to 50 subjects at no direct cost to the project. Above 50 letters postage will be charge back at \$0.46 per hand addressed envelope. The charge drops to \$0.40 if addressed by machine. For further details please contact the mail room directly.