ISMMS PPHS Certificate of Confidentiality (COC) Notification Plan and Certification

Project Number (HSM/GCO/IRB):________________________________

Project Title:________________________________________________

Principal Investigator:_________________________________________

By signing below, I certify:

1. The project is funded by NIH and involves human subjects, generation of identifiable information or samples, or involves the generation of individual level, human genomic data.

2. The project was not granted a COC before 10/1/2017

3. I and my research team will NOT

   • Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or

   • Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains.

       o This does not prohibit the disclosure of information under mandated reporting, such as threats of harm to self or others.

4. Any consent form submitted after 10/1/17 will incorporate IRB approved COC language.

Furthermore (circle either A or B):

A. I will send out notices to (fill in number)_________subjects by mail, email, and/or phone calls, maintain documentation of completion and will notify the PPHS if this is not complete as of 10/31/17.

OR

B. Either I, or a research team member already authorized to get consent, will personally meet with all human subjects to provide them with notification, answer all questions, and will notify the PPHS if this is not complete as of 11/30/2017.

__________________________

Print Name

__________________________

Date

__________________________

Signature

Ver. 1 October 1, 2017