Changes to Certificates of Confidentiality as of 10/1/17

The NIH announced earlier this month that they will be adopting a new policy regarding the issuance of certificates of confidentiality (COC). These changes may impact both research teams and participants and can require contacting research participants. The following is the PPHS’s understanding and advice as of 9/28/17.

1-If the project is not NIH funded there is nothing to do and nothing changes in how to go about requesting a certificate.

2-If the project already has a certificate there is nothing to do and nothing changes.

3-If the project is NIH funded and was active on 12/31/16 or commenced after that date, the project will be automatically granted a COC on 10/1/17 if the project involves human subjects, activities using or generating identifiable human subject data or samples, or involves the generation of individual level, human genomic data. This means:

1. Involved research teams are now bound by the COC and must 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.
	+ This does not prohibit the disclosure of information under mandated reporting, such as threats of harm to self or others.
1. Enrolled, consented subjects must be notified about these new privacy protections. The PPHS has drafted a letter that can be used. Notification is the responsibility of the individual PI and must be completed in an expeditious manner. Personal notification during an upcoming research visit is acceptable, but if no near future visit is planned then mail, email or phone should be used. More details about notification methods , IRB reporting requirements and mailing logistics will be available next week and will be discussed at the 10/4 Clinical Research Forum (Davis Auditorium, Hess Bldg 12-1 p.m.).
2. **At the time of any modification of the consent, or at the time of annual continuation the consent must incorporate COC language (to be supplied by the PPHS).**

4-NIH projects involving human subjects, or activities using or generating identifiable human subject data or samples, or involves the generation of individual level, human genomic data approved after 10/1/17 will need appropriate COC language in the proposed consents.

Short-term Next steps:

Investigators:

1. Determine if you are impacted by this change, i.e. you have an open NIH funded project without a COC but which involves human subjects or activities using or generating identifiable human subject data or samples, or involves the generation of individual level, human genomic data.
2. Determine the number of subjects that need to be notified.
3. Determine if the project’s protocol will allow you to meet face to face with each subject in the near future.
4. Determine if you have physical addresses, emails and/or phone contacts for the subjects.

PPHS activities:

* By the end of September: Update PPHS website landing page for COC’s. This will initially include current information, the official notice from the NIH and the letter drafted by the PPHS to use for notification.
* By 10/4/17 Updated COC language for use in consents will be posted on the PPHS website.
* By 10/4/17 develop and post a report form to be filed with the PPHS selecting the notification option and timeline. As long as there is no deviation from the timeline, there will be no further need to notify the PPHS.
* By 10/4/17 develop concrete guidance about mailing logistics, notification methods, costs, etc. to be discussed at the Clinical Research Forum and posted online.